

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

HELEN McLAUGHLIN	:	CIVIL ACTION NO. 14-7315
	:	
v.	:	
	:	
	:	NO. 18-1144 (Archambault) NO. 18-1153 (Reiss)
BAYER ESSURE, INC., et al.	:	NO. 18-1146 (Brenner) NO. 18-1154 (Reynolds)
	:	NO. 18-1147 (Dawson) NO. 18-1155 (Ross)
And Related Actions	:	NO. 18-1148 (Dixson) NO. 18-1156 (Rubio)
	:	NO. 18-1149 (Goins) NO. 18-1157 (Wayne)
	:	NO. 18-1150 (Hyer) NO. 18-1158 (Young)
	:	NO. 18-1151 (Jacobs) NO. 18-1162 (Hentz)
	:	NO. 18-1152 (Parker) NO. 18-1959 (Riley)

**MEMORANDUM**

**Padova, J.**

**July 23, 2018**

Each female Plaintiff in these sixteen consolidated actions, which Defendants have removed from the Court of Common Pleas of Philadelphia County, seeks compensation for injuries she sustained in connection with her use of Essure, a birth control device.<sup>1</sup> Plaintiffs now seek to remand the cases back to state court, arguing that we have no subject matter jurisdiction over the disputes. For the following reasons, we grant the Motions to Remand.<sup>2</sup>

**I. BACKGROUND**

Plaintiffs commenced all sixteen of these actions in the Court of Common Pleas of Philadelphia County. The Defendants in each case are Bayer Corp.; Bayer U.S. LLC; Bayer Healthcare LLC; Bayer Essure, Inc.; Bayer Healthcare Pharmaceuticals, Inc.; Bayer AG; Bayer Pharma AG; Conceptus SAS; and Bayer S.A. (collectively “Bayer”). The Complaints describe

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<sup>1</sup> The lead case, McLaughlin v. Bayer Essure, Inc., Civil Action No. 14-7315, unlike the other cases in the caption, was not removed to this Court. However, it is the case under which all of the Essure cases are consolidated in this District. Accordingly, it is included in the case caption even though the Motions that we address are only pertinent to the other sixteen cases.

<sup>2</sup> There have been two Motions to Remand filed. One pertains to the first fifteen cases, which Defendants removed to this Court on March 16, 2018, and the second concerns only Riley v. Bayer Essure, Inc., Civil Action No. 18-1959, which was not removed until May 9, 2018. The briefing on the two Motions, however, is identical in all material respects.

Essure as metal coils, which are placed in a woman's fallopian tubes and are intended to block the tubes and prevent pregnancy. (See Archambault Compl. ¶¶ 33, 49, 51.<sup>3</sup>) Essure is a Class III medical device that received "Conditional Premarket Approval" from the Food and Drug Administration (the "FDA") before it was marketed to the public. (Id. ¶¶ 35, 66-67, 73.) The Complaints allege that, instead of working as intended, the Essure device "migrates from the [fallopian] tubes, perforates organs, breaks into pieces, and/or corrodes." (Id. ¶ 33.) Each Plaintiff had Essure implanted and, as a result, suffered "severe and permanent injuries." (Id. ¶¶ 33, 117.)

The Complaints assert state law claims of negligent training, negligent risk management, breach of express warranty, negligent misrepresentation, and negligent failure to warn. The negligent training claim (Count I) asserts that Bayer undertook to train physicians to implant Essure and did so negligently. (Id. ¶¶ 170, 175, 178.) The negligent risk management claim (Count II) asserts that Bayer failed to engage in reasonable risk management insofar as it failed to notify the FDA of adverse reports regarding Essure, failed to consider the adverse reports in its own risk analysis, and failed to track non-conforming product. (Id. ¶¶ 184, 187, 190.) The breach of express warranty claim (Count III) asserts that various statements concerning Essure's qualities, safety, and efficacy that Bayer made in promotional materials and on its website, constituted express warranties, and that Bayer breached those warranties. (Id. ¶¶ 197-98, 203.) The negligent misrepresentation claim (Count IV) asserts that the same statements that constituted express warranties also constituted negligent misrepresentations. (Id. ¶¶ 209, 212-13.) The negligent failure to warn claim (Count V) asserts that Bayer failed to warn Plaintiffs

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<sup>3</sup> As all sixteen Complaints are largely identical, we will cite exclusively to the Complaint in Achambault, Civil Action No. 18-1144, for ease of reference.

and the implanting physicians of the risks of the device and manufacturing defects by failing to file required adverse reports with the FDA. (Id. ¶¶ 219- 21.)

Bayer timely removed the cases to this Court, asserting that we have federal question jurisdiction over all of the cases. Bayer asserts that we also have diversity jurisdiction over those cases involving Plaintiffs who are not citizens of Pennsylvania.<sup>4</sup> Plaintiffs have filed Motions to Remand the cases to the Court of Common Pleas of Philadelphia County.

## **II. LEGAL STANDARD**

The federal removal statute provides, in relevant part, as follows:

Except as otherwise expressly provided by Act of Congress, any civil action brought in a State court of which the district courts of the United States have original jurisdiction, may be removed by the defendant or the defendants, to the district court of the United States for the district and division embracing the place where such action is pending.

28 U.S.C. § 1441(a). This Court can assert original jurisdiction over cases based either on diversity of citizenship, 28 U.S.C. § 1332(a), or federal question jurisdiction, 28 U.S.C. § 1331.

Once a case is removed, the federal court must remand if it determines that it lacks original federal subject matter jurisdiction. See 28 U.S.C. §1447(c). The removing party bears the burden of proving the existence of federal subject matter jurisdiction. Boyer v. Snap-on Tools Corp., 913 F.2d 108, 111 (3d Cir. 1990). Courts strictly construe the removal statute and resolve all doubts in favor of remand. Id.

## **III. DISCUSSION**

### **A. Diversity Jurisdiction**

In their Notices of Removal in the cases involving Plaintiffs who are not Pennsylvania citizens, Bayer asserts that we may assert diversity jurisdiction because the Plaintiffs are diverse

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<sup>4</sup> Five cases involve Plaintiffs who not citizens of Pennsylvania: Dixson, Goins, Hylar, Reynolds, and Riley.

from Bayer and the amount in controversy exceeds \$75,000. See 28 U.S.C. § 1332(a). Plaintiffs do not dispute that the amount in controversy in each case exceeds \$75,000 or that the parties are diverse from one another, but they argue that the Forum Defendant Rule prohibits Bayer from removing based on diversity of citizenship.

Pursuant to the Forum Defendant Rule, “[a] civil action otherwise removable solely on the basis of [diversity] jurisdiction . . . may not be removed if any of the parties in interest properly joined and served as defendants is a citizen of the State in which such action is brought.” 28 U.S.C. § 1441(b)(2). Here, Bayer’s Notices of Removal specifically assert that one Defendant, Bayer Healthcare LLC, is a citizen of Pennsylvania. (See, e.g., Archambault Notice of Removal, Docket No. 1, at ¶ 18; see also id. ¶ 26.) Moreover, Bayer does not attempt to argue in its Memorandum in Opposition to Plaintiff’s Motion to Remand that the Forum Defendant Rule does not apply here to prohibit removal based on diversity jurisdiction and, instead, argues only that we have federal question jurisdiction over the case. Accordingly, we conclude that, pursuant to the Forum Defendant Rule, Bayer cannot base its removal of any of these cases on diversity of citizenship jurisdiction.

## **B. Federal Question Jurisdiction**

Bayer asserts in all sixteen Notices of Removal that we have federal question jurisdiction over the cases pursuant to Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg., 545 U.S. 308, 312 (2005), because Plaintiffs’ state law claims turn on a construction of federal law.

Federal district courts “have original jurisdiction of all civil actions arising under the Constitution, laws, or treaties of the United States.” 28 U.S.C. § 1331. Federal question jurisdiction pursuant to § 1331 is typically invoked in cases in which the plaintiff “plead[s] a cause of action created by federal law.” Manning v. Merrill Lynch Pierce Fenner & Smith, Inc.,

772 F.3d 158, 162-63 (3d Cir. 2014) (citing Grable, 545 U.S. at 312) (additional citations omitted). “However, [state law] causes of action . . . may nonetheless ‘arise under’ federal law for purposes of [federal question jurisdiction] if the four-pronged Grable test is met.” Id. at 163. The Grable test provides that a court will have federal question jurisdiction over a state law claim “‘if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.’” Id. (quoting Gunn v. Minton, 568 U.S. 251, 258 (2013)). Notably, “[o]nly a ‘slim category’ of cases satisfy the Grable test.” Id. (quoting Empire Healthchoice Assurance, Inc. v. McVeigh, 547 U.S. 677, 701 (2006)).

Here, as noted above, Plaintiffs’ Complaints assert five state law causes of action, four sounding in tort and one sounding in contract, and all of which seek compensation for injuries Plaintiffs sustained as a result of their use of Essure, a Class III medical device. Pursuant to the Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.* (the “MDA”), state law claims concerning Class III medical devices are expressly preempted by federal law if they seek to impose requirements that are “different from, or in addition to” those imposed by federal law. Riegel v. Medtronic, Inc., 552 U.S. 312, 321 (2008) (quoting 21 U.S.C. § 360k(a)(1)). The MDA’s express preemption provisions “do[] not[, however,] prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” Id. at 330 (quoting Medtronic, Inc. v. Lohr, 518 U.S. 470, 495 (1996), and citing Lohr, 518 U.S. at 513).

Given these preemption principles, Plaintiffs have pleaded federal requirements that “parallel” the state law duties on which they base their state law claims so as to avoid express preemption. They therefore concede for purposes of their Motions to Remand that issues of

federal law are “necessarily raised” by their state law claims. See MHA LLC v. HealthFirst, Inc., 629 F. App’x 409, 412-13 (3d Cir. 2015) (explaining that a state law claim necessarily raises a federal issue if “an element of the state law claim requires construction of federal law” (citing Manning, 772 F.3d at 163)).<sup>5</sup> They argue, however, that we do not have federal question jurisdiction pursuant to Grable because the issues of federal law are not actually disputed or substantial, and are not capable of resolution without disrupting the federal-state balance. In contrast, Bayer maintains that all four Grable requirements are met in this case and, thus, we should assert federal question jurisdiction.

### **1. Actually Disputed and Substantial**

As Bayer is the party asserting federal jurisdiction, it bears the burden of proving that there are federal legal issues in these cases that are both actually disputed and substantial. See Boyer, 913 F.2d at 111. In determining whether an issue of federal law is “substantial,” we “look[] . . . to the importance of the issue to the federal system as a whole.” Gunn, 568 U.S. at 260. “The prototypical case of Grable jurisdiction is one in which the federal government itself seeks access to a federal forum, an action of the federal government must be adjudicated, or where the validity of a federal statute is in question.” MHA LLC, 629 F. App’x at 413 n.6 (citing Gunn, 568 U.S. at 260, and Grable, 545 U.S. at 213). In contrast, the substantiality requirement is not typically met where the issue is significant only to the parties. Id. at 413

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<sup>5</sup> We take no position as to whether the law supports Plaintiffs’ concession. We note only, by way of comparison, that a federal District Court in California recently held that a complaint in an Essure case did not satisfy the “necessarily raised” prong of the Grable test. See Sangimino v. Bayer Corp., Civ. A. No. 17-1488, 2017 WL 2500904, at \*2-3 (N.D. Ca. June 9, 2017). That court reasoned that a preemption defense cannot provide the basis for federal-question jurisdiction even if the defense is anticipated in the plaintiff’s complaint, and that allegations of federal law violations do not provide a basis for jurisdiction where the plaintiff’s claims are also supported by alternative and independent state law theories. See id. (citations omitted).

(citing Gunn, 568 U.S. at 258-59). Indeed, in applying Grable, “the Supreme Court has distinguished cases . . . that present a ‘nearly pure issue of law’ that would govern numerous other cases, from those that are ‘fact-bound and situation-specific.’” Id. (quoting Empire Healthchoice, 547 U.S. at 700-01). In assessing substantiality, the absence of a federal cause of action is relevant but not dispositive. Grable, 545 U.S. at 318 (citing Merrell Dow Pharm. v. Thompson, 478 U.S. 804 (1986)).

Here, the federal government is not seeking access to a federal forum, no action of the federal government is being adjudicated, and there is no question about the validity of a federal statute. See MHA LLC, 629 F. App’x at 413 n.6. Thus, this is not a “prototypical case of Grable jurisdiction.” Id. (citations omitted). Bayer contends, however, that the case presents actually disputed and substantial issues of federal law.

As an initial matter, Bayer emphasizes that Essure is heavily regulated by the FDA, and it argues that Plaintiffs’ claims will turn on the interpretation of federal law insofar as they hinge on whether Bayer violated federal regulatory requirements. It further emphasizes that the Complaints recite numerous federal regulations and repeatedly allege that Bayer is liable under state law because it breached duties set forth in the federal regulatory requirements. (See, e.g., Archambault Compl. ¶¶ 185, 220-21.) In asserting that these federal issues, which Plaintiffs have conceded are necessarily raised, are also both “actually disputed” and “substantial,” Bayer asserts that it “vigorously disputes Plaintiffs’ allegations that it violated federal law” and contends that the disputes concern an interpretation of federal law, not merely the application of federal law to the facts of the case. (Bayer’s Opposition to Pls.’ Mot. to Remand at 7.) Specifically, Bayer contends that the disputes concern “the meaning of the federal regulation governing the duty to report adverse events, 21 C.F.R. § 803.50,” including the type of

information Congress and the FDA require to be disclosed.<sup>6</sup> It also contends that there is a disputed issue regarding “Conditional Pre-Market Approval,” because it disagrees with Plaintiff’s assertion that there is a recognized legal status called “Conditional Pre-Market Approval,” as well as Plaintiffs’ assertion that devices receiving such approval may not be marketed if the conditions in the approval order are violated. (Id.)

Bayer does not, however, further elaborate on these purported disputes and, thus, has not met its burden of establishing that they are “actually disputed” and “substantial.” Indeed, Bayer does not specify the particular regulatory language within 21 C.F.R. § 803.50 that is subject to differing interpretations and does not identify any other specific Congressional or FDA reporting requirement about which the parties disagree. Likewise, while Bayer suggests that there is a dispute regarding the existence and significance of “Conditional Pre-Market Approval,” it fails to elaborate on the precise contours of that dispute or explain how it is central to the resolution of Plaintiffs’ claims here. (Id.) As a result, Bayer has simply not established that there is an actual disagreement about an interpretation of federal law that is material to the claims at issue. See MHA LLC, 620 F. App’x at 414 (finding no “actually disputed” federal issue where the party seeking federal jurisdiction had failed to “identif[y] a dispute over the meaning of particular statutory text” and instead only “generally aver[red] that the parties disagree over the application

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<sup>6</sup> Section § 803.50 requires a manufacturer of a medical device to report to the FDA certain information that is reasonably known to it:

no later than 30 calendar days after the day that you receive or otherwise become aware of information . . . that reasonably suggests that a device that you market . . . [m]ay have caused or contributed to a death or serious injury, or [h]as malfunctioned and . . . would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

21 C.F.R. § 803.50(a); id. § 803.52. Information is considered to be “reasonably known” to the manufacturer if, inter alia, it is in the manufacturer’s possession or the manufacturer can obtain the information by analysis, testing, or other evaluation of the device. Id. § 805.50(b)(1).

of the [statute] to their situation.”) Moreover, it has not established that the resolution of any dispute would have ramifications in federal cases outside of the Essure context or is otherwise important to the “federal system as a whole.”<sup>7</sup> Gunn, 568 U.S. at 260. Indeed, we conclude that Bayer has failed to identify any federal issue that holds significance for anyone other than the parties. See MHA LLC, 629 F. App’x at 413 (requiring issue to be “significant ‘to the federal system’” as opposed to only the parties (quoting Gunn, 568 U.S. at 260)); see also Congregation Machna Shalva Zichron Zvi Dovid v. U.S. Dept. of Agric., 557 F. App’x 87, 90 (2d Cir. 2014) (affirming district court decision not to exercise federal question jurisdiction under Grable where “the determination at issue . . . [was] a fact-specific application of the regulations to [the plaintiff] that does not implicate the validity of the regulations themselves, or have any other broader effect on federal interests”).

Furthermore, it is important to reiterate that although the Complaints in these cases allege that Bayer violated federal law, the central claims in the Complaints are that Bayer violated state law and the Complaints merely reference federal law to rebut any argument that their state law claims are preempted. See Newsome v. Bayer Corp., Civ. A. No. 17-57, 2018 WL 1906103, at \*2 (E.D. Ky. Apr. 23, 2018) (expressing doubt in an Essure case that “litigation regarding the defendants’ state duties—duties that merely parallel federal law—will necessarily raise a disputed federal issue”). Under these circumstances, we conclude that Bayer has failed to meet its burden

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<sup>7</sup> Bayer contends that there is powerful federal interest in uniform interpretation and application of FDA regulations concerning Class III medical devices because proper application of the regulations advances the federal interest in permitting the sale and marketing of certain devices that offer significant public health benefits in spite of their admitted risks. While we do not dispute this general premise, in the absence of a specifically-identified dispute as to the meaning of the federal regulations, we have no basis on which to conclude that resolution of that dispute in this action would provide a rule of general applicability that would affect the regulation of other Class III medical devices.

of establishing that these cases raise any substantial federal issue that is actually disputed, and we decline to exercise Grable jurisdiction for that reason.

## **2. Federal-State Balance**

While we decline to exercise federal question jurisdiction under Grable because Bayer has failed to identify a substantial and actually disputed federal issue, we also conclude that we have no such jurisdiction here because Bayer has failed to establish that exercising jurisdiction over these cases would not upset the federal-state balance. Even when a case does present “a contested and substantial federal question,” it can only “qualify for a federal forum . . . if federal jurisdiction is consistent with congressional judgment about the sound division of labor between state and federal courts governing the application of § 1331.” Grable, 545 U.S. at 313-14. “[T]he appropriateness of a federal forum to hear an embedded issue [can] be evaluated only after considering the ‘welter of issues regarding the interrelation of federal and state authority and the proper management of the federal judicial system.’” Id. at 314 (quoting Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Tr. for S. Cal., 463 U.S. 1, 28 (1983)).

Bayer contends that the issues raised in this case are of special concern to the federal system because they concern Class III medical devices, which are subject to stringent federal scrutiny. It cites with approval a federal District Court in North Carolina, which found that it had federal question jurisdiction over an Essure case, stating with respect to the federal-state balance that “[i]t does not upset the federal-state balance to allow federally-approved medical devices to be sued for alleged safety risks and labeling defects in federal court” because “[t]he labeling of FDA-approved medical devices is governed by the FDA under the MDA, and [the] state law is generally pre-empted under 21 U.S.C. § 360k.” Burrell v. Bayer Corp., Civ. A. No. 17-31, 2017 WL 1032524, at \*4 (W.D.N.C. Mar. 17, 2017).

We, however, decline to follow the logic of Burrell and, instead, align ourselves with other recent cases that have found the exercise of jurisdiction over Essure cases to disrupt the federal-state balance. See Newsome v. Bayer Corp., Civ. A. No. 17-57, 2018 WL 1906103, at \*4 (E.D. Ky. Apr. 23, 2018); Johnson v. Bayer Corp., Civ. A. No. 16-729, 2016 WL 3015187, at \*3 (E.D. Mo. May 26, 2016) (specifically concluding that “the federal issues raised by plaintiffs’ state law claims are not capable of resolution in federal court without disrupting the federal-state balance approved by Congress” (citation omitted)). We certainly agree with Bayer that Congress has a significant interest in the regulation of Class III medical devices. Riegel, 552 U.S. at 316 (recognizing that the MDA “impose[s] a regime of detailed federal oversight” over the design, labeling, and marketing of such devices). We nevertheless read the MDA and the Supreme Court’s decision in Riegel to make clear that Congress intended for the state courts to resolve cases such as this one, which ask whether a defendant violated state laws that parallel federal requirements applicable to Essure. Indeed, as noted above, the MDA’s preemption of state law only preempts “state requirements [that are] ‘different from, or in addition to, any [federal] requirement applicable . . . to [a] device’ under federal law.” Id. at 321 (third alteration in original) (quoting 21 U.S.C. § 360k(a)(1)). Moreover, Congress provided no corresponding private federal cause of action for violation of federal requirements. See Buckman Co. v. Plaintiffs’ Legal Comm., 531 U.S. 341, 349 n.4 (2001) (stating that that “‘all . . . proceedings for the enforcement, or to restrain violations, of [the MDA] shall be by and in the name of the United States’”) (quoting 21 U.S.C. § 337(a)). Thus, under the Congressionally-designed scheme, the MDA permits individuals to bring state law causes of action alleging violations of duties that parallel the federal requirements. It would be entirely inconsistent with this structure to conclude that Congress intended all such state law causes of action to be brought in federal

court. See Grable, 545 U.S. at 318 (observing that the Supreme Court, in Merrell Dow, “treated the combination of no federal cause of action and no preemption of state remedies for misbranding as an important clue to Congress’s conception of the scope of jurisdiction to be exercised under § 1331” (citing Merrell Dow, 478 U.S. 804)). To hold otherwise under the circumstances here would be to “welcome any state-law tort case implicating federal law ‘solely because the violation of the federal statute is said to [support a claim of negligence] under state law.’” Id. at 319 (quoting Merrell Dow, 478 U.S. at 811-12).

We therefore conclude that Bayer has failed to establish that exercising federal question jurisdiction over these cases would not upset the federal-state balance. For this reason, as well as because Bayer has failed to establish that these removed cases raise an actually disputed and substantial federal issue, we decline to exercise federal question jurisdiction over the cases and instead remand them to state court.

#### **IV. CONCLUSION**

For the foregoing reasons, we conclude that Bayer has failed to carry its burden of showing that we have either diversity or federal question jurisdiction over these cases. We therefore grant Plaintiffs’ Motions to Remand, and we remand these sixteen removed cases to the Court of Common Pleas of Philadelphia County. An appropriate Order follows.

BY THE COURT:

/s/ John R. Padova, J.

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John R. Padova, J.

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**ORDER**

**AND NOW**, this 23rd day of July, 2018, upon consideration of Plaintiffs' Motions to Remand, and all documents filed in connection therewith, **IT IS HEREBY ORDERED** as follows:

1. The Motions to Remand are **GRANTED**.
2. The above-captioned cases (with the exception of McLaughlin v. Bayer Essure, Civ. A. No. 14-7315) are **REMANDED** to the Court of Common Pleas of Philadelphia County.
3. The Clerk of Court is **DIRECTED** to **CLOSE** the above-captioned cases (with the exception of McLaughlin).

BY THE COURT:

/s/ John R. Padova, J.

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John R. Padova, J.