PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 17-1715

KRISTIANA TWEED BURRELL, individually and as Administratrix of the Estate of Ariel Grace Burrell; TRAVIS BURRELL,

Plaintiffs - Appellants,

v.

BAYER CORPORATION, an Indiana corporation; BAYER HEALTHCARE LLC, a Delaware corporation; CHRISTOPHER FORD WILLIAMS; STACY D. TRAVIS, Dr.; BILTMORE OB-GYN, P.A.; BAYER ESSURE INC., f/k/a Conceptus, Inc., a Delaware corporation; BAYER HEALTHCARE PHARMACEUTICALS, INC., a Delaware corporation,

Defendants - Appellees.

Appeal from the United States District Court for the Western District of North Carolina, at Asheville. Max O. Cogburn, Jr., District Judge. (1:17-cv-00031-MOC-DCK)

Argued: October 30, 2018 Decided: March 14, 2019

Before FLOYD and HARRIS, Circuit Judges, and Donald C. COGGINS, Jr., United States District Judge for the District of South Carolina, sitting by designation.

Vacated and remanded by published opinion. Judge Harris wrote the opinion, in which Judge Floyd and Judge Coggins joined.

ARGUED: Tejinder Singh, GOLDSTEIN & RUSSELL, P.C., Washington, D.C., for Appellants. Erika L. Maley, SIDLEY AUSTIN LLP, Washington, D.C., for Appellees. **ON BRIEF:** George Fleming, Rand P. Nolen, Jessica Kasischke, Sylvia Davidow,

FLEMING, NOLEN & JEZ, L.L.P., Houston, Texas; Thomas C. Goldstein, GOLDSTEIN & RUSSELL, P.C., Bethesda, Maryland, for Appellants. Jonathan F. Cohn, Virginia A. Seitz, Christopher A. Eiswerth, Morgan Branch, SIDLEY AUSTIN LLP, Washington, D.C., for Appellees.

PAMELA HARRIS, Circuit Judge:

Kristiana Tweed Burrell and her husband filed suit against Bayer in connection with a female sterilization device known as Essure, alleging that Burrell suffered a stillbirth and then underwent a hysterectomy due to complications from the device. The Burrells commenced this action in North Carolina state court, seeking damages for violations of North Carolina tort and products liability law.

The issue we confront in this appeal is not the merits of the Burrells' claims, but whether those claims should be heard in state or federal court. According to Bayer, this is a federal case: Although the Burrells seek relief under state law, their claims necessarily implicate significant questions regarding Bayer's compliance with federal regulations and thus give rise to federal question jurisdiction under 28 U.S.C. § 1331. We disagree. As the Supreme Court has emphasized, § 1331 confers federal jurisdiction over state-law causes of action only in a "special and small" class of cases. *Empire HealthChoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 699 (2006). Because the Burrells' state-law action against Bayer does not fall within that special class, it should be decided by North Carolina's courts. We therefore vacate the district court's contrary judgment and direct that the case be remanded to state court.

I.

A.

The crux of Bayer's argument for federal question jurisdiction is that because Essure is regulated by the federal government, the Burrells' suit regarding Essure will

require the resolution of important federal-law questions. We begin by briefly describing the federal laws and regulations that govern Essure, to provide necessary context for Bayer's position and the proceedings in this case.

Essure is a permanent female contraceptive consisting of metal coils, known as "micro-inserts," inserted into a woman's fallopian tubes. Once released through a disposable delivery system, the micro-inserts expand and anchor in the fallopian tubes, causing fibrous tissue growth that blocks the tubes and prevents pregnancy.

Essure is regulated by the Food and Drug Administration ("FDA") as a Class III medical device, under the 1976 Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act"). Class III devices are subject to the most stringent oversight under the Act, *see* 21 U.S.C. § 360c(a)(1)(C), and a novel Class III device like Essure cannot be distributed until it receives premarket approval from the FDA, *id.* § 360e. Following premarket approval, a manufacturer cannot amend the device design without FDA sign-off, can make only limited changes to the device's labeling, and must submit to the FDA information regarding adverse events related to the device,[1] among other requirements. *See id.* §§ 360e(d)(5)(A)(i), 360i(a); 21 C.F.R. § 814.39(a), (d).

[1] Specifically, a manufacturer like Bayer must report to the FDA any instance in which its approved device "may have caused or contributed to a death or serious injury," and any malfunction that would "be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 U.S.C. § 360i(a)(1)(A)–(B).

The Act does not establish a private right of action to enforce these requirements under federal law. With respect to state-law remedies, the Act includes an express preemption provision, prohibiting states from imposing requirements on premarket-approved Class III medical devices – like Essure – that are "different from, or in addition to" federal requirements. 21 U.S.C. § 360k(a). That leaves room, as the Supreme Court has explained, for state-law remedies for violations of common-law duties that "parallel" federal regulatory requirements. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008). A claim that a Class III device "violated state tort law *notwithstanding compliance* with the relevant federal requirements" would be preempted under § 360k(a), because it seeks to impose "addition[al]" state-law requirements on the federally-approved device. *Riegel*, 552 U.S. at 330 (emphasis added). But a claim "premised on a *violation* of FDA regulations" is not preempted, because "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* (emphasis added).

Essure received premarket approval from the FDA in 2002. Accordingly, the Burrells may proceed against Bayer under North Carolina law consistent with § 360k(a) to the extent (and only to the extent) that the state-law duties on which they rely "parallel" the federal requirements that apply to Essure. What relief is available under North Carolina law is of course a question of state and not federal law.

B.

Kristiana Tweed Burrell received an Essure implantation in December 2013. According to Burrell, tests performed in the ensuing months found that the device was

causing only a partial blockage of her left fallopian tube, and thus failing to provide contraceptive protection.

On June 5, 2015, Burrell discovered that she was pregnant when she felt fetal movement. Two days later, she experienced abdominal pain and vaginal bleeding, and went into premature labor at home. Burrell was admitted to the hospital, where her baby was delivered stillborn at an estimated 24 to 27 weeks. Burrell was diagnosed with placental abruption, a serious pregnancy complication in which the placenta prematurely separates from the uterus. Subsequent doctor visits confirmed that Burrell's Essure implant had failed and was eroding through the left fallopian tube. To remove the device, Burrell then was required to undergo a total hysterectomy – that is, a surgical procedure to remove her uterus.

In December 2016, Burrell and her husband filed separate lawsuits in North Carolina state court against the Bayer Corporation and related defendants (collectively, "Bayer").[2] The lawsuits, later consolidated, seek damages for personal injuries, emotional distress, and wrongful death under various state-law causes of action, relying primarily on four core allegations. First and most prominently, the Burrells allege that Bayer failed to disclose to the medical community or the FDA numerous adverse events similar to those they experienced, depriving them of proper warning about Essure's risks.

[2] The Burrells also sued the obstetrician-gynecologist and medical practice that performed the implantation, alleging medical malpractice under North Carolina law. The district court ultimately declined to exercise supplemental jurisdiction over that claim, so it is not addressed or affected by our decision today.

Second, they assert that Bayer failed to update its labeling and marketing materials to reflect these risks, further depriving them of adequate warning. Third, they claim that Bayer sold Essure implants with manufacturing defects, suggesting that one of these defects may have been present in Burrell's implant and caused her injuries. And fourth, they allege that Bayer did not adequately train doctors, including Burrell's obstetrician-gynecologist, on the implantation procedure, despite informing the public otherwise.

That conduct, according to the complaints, violated state law in multiple respects. Specifically, the complaints assert the following causes of action against Bayer under North Carolina law: that Bayer was negligent and breached its duty to warn the Burrells of known dangers regarding Essure; that Essure was unreasonably dangerous in violation of state products liability law; that Bayer breached both express and implied warranties; and that Bayer engaged in fraud and unfair or deceptive trade practices. In anticipation of a federal preemption defense, as outlined above, the complaints also allege that Bayer violated numerous federal regulatory requirements that purportedly parallel Bayer's duties under state law.

C.

The jurisdictional question at issue in this appeal arose when Bayer removed the Burrells' actions to federal court, invoking 28 U.S.C. § 1441. Under that provision, Bayer was entitled to remove the case only if the Burrells' state-law claims could have been brought in federal court originally, based on some independent source of federal jurisdiction. *See Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808 (1986). Because the parties to this case are not diverse for purposes of diversity jurisdiction under

28 U.S.C. § 1332, Bayer's notice of removal identified one and only one basis for federal jurisdiction: 28 U.S.C. § 1331, conferring what is known as federal question jurisdiction over civil actions "arising under" federal law.

Cases generally are deemed to "arise under" federal law when it is federal law, not state law, that creates the cause of action. *See Merrell Dow*, 478 U.S. at 808. But Bayer argued that the Burrells' case falls within an exception to that general rule because their state-law claims necessarily raise substantial federal-law questions. The Burrells' complaints, Bayer noted, contained multiple references to federal regulatory requirements allegedly violated by Bayer. And because the Burrells' state-law claims would be preempted unless Bayer had violated parallel federal duties, their right to relief necessarily required resolution of those federal-law questions. Moreover, given the FDA's extensive oversight of Essure, whether Bayer had lived up to its regulatory obligations was a matter of sufficient federal importance that it warranted adjudication in a federal forum.

The district court agreed, denying the Burrells' motion to remand the case to state court and retaining jurisdiction under § 1331. The court began by laying out the "four-part test" that governs whether a lawsuit based on state-law claims gives rise to federal question jurisdiction: To come within § 1331, the case must feature a state-law claim that (1) "necessarily raise[s]" a federal issue, and that federal issue must be "(2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress." J.A. 1130 (quoting *Gunn v. Minton*, 568 U.S. 251, 258 (2013)).

As to the first two prongs – whether the Burrells' state-law claims "necessarily raise[]" disputed federal issues – the court essentially adopted Bayer's argument. The Burrells' complaints, the court reasoned, are "replete with references to the FDA" and allegations that Bayer failed to comply with its federal regulatory duties. J.A. 1131. As a result of the Act's express preemption provision, the court continued, the Burrells cannot succeed on their state-law claims unless they can show that Bayer in fact deviated from those federal requirements. "Accordingly, [the federal regulations governing Essure] are implicated here and in dispute." J.A. 1133.

The court relied again on the Act's preemptive effect under the latter two prongs of the analysis. Because "state law is generally pre-empted" under § 360k(a), the court determined, "[i]t does not upset the federal-state balance to allow [manufacturers of] federally-approved medical devices to be sued . . . in federal court." J.A. 1136. And because what is at issue is "federal oversight of Class III medical device products," the district court further reasoned, the dispute as to federal law is "substantial." *Id.*

Having retained jurisdiction, the court two months later granted Bayer's motion to dismiss the Burrells' case, largely on preemption grounds. *See Burrell v. Bayer Corp.*, 260 F. Supp. 3d 485 (W.D.N.C. 2017). The Burrells timely appealed, challenging both the district court's exercise of jurisdiction and the dismissal of their case on the merits.

II.

We begin and end with the district court's jurisdictional holding. "Subject matter jurisdiction defines a court's power to adjudicate cases or controversies – its adjudicatory

authority – and without it, a court can only decide that it does not have jurisdiction." *United States v. Wilson*, 699 F.3d 789, 793 (4th Cir. 2012). If the Burrells' case "was not properly removed, because it was not within the original jurisdiction of the United States district courts," then the district court was without jurisdiction to rule on its merits and instead was required to remand the action to state court. *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust*, 463 U.S. 1, 8 (1983) (citing 28 U.S.C. § 1447(c)). We review the district court's jurisdictional holding de novo, *Mulcahey v. Columbia Organic Chems. Co.*, 29 F.3d 148, 151 (4th Cir. 1994), and conclude that it was in error. Accordingly, this case must be remanded to state court for proceedings on the merits.

A.

Under 28 U.S.C. § 1331, federal courts have federal question jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." In the "vast majority of cases," that means suits "in which federal law creates the cause of action." *Merrell Dow*, 478 U.S. at 808; *see also Dixon v. Coburg Dairy, Inc.*, 369 F.3d 811, 816 (4th Cir. 2004) (en banc). This case is about the exception to that rule – the "slim category" of cases, *Gunn*, 568 U.S. at 258, in which state law supplies the cause of action but federal courts have jurisdiction under § 1331 because "the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law," *Franchise Tax Bd.*, 463 U.S. at 28.

As the Supreme Court has emphasized, courts are to be cautious in exercising jurisdiction of this type, which lies at "the outer reaches of § 1331." *Merrell Dow*, 478 U.S. at 810. The "mere presence of a federal issue in a state cause of action" is not

enough to confer jurisdiction. *Id.* at 813. If it were, then innumerable claims traditionally heard in state court would be funneled to federal court instead, raising "serious federal-state conflicts." *Franchise Tax Bd.*, 463 U.S. at 10. To avoid those conflicts and ensure that state-law claims only rarely give rise to § 1331 jurisdiction, the Supreme Court has established the four-pronged test outlined by the district court in this case: The federal question must be "necessarily raise[d]" and "actually disputed" by the parties. *Grable & Sons Metal Prods. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005). It also must be "substantial," *id.*, meaning that its resolution is "importan[t] . . . to the federal system as a whole," *Gunn*, 568 U.S. at 260. And, finally, the federal system must be able to hear the issue "without disturbing any congressionally approved balance of federal and state judicial responsibilities." *Grable*, 545 U.S. at 314.

Applying those factors, a substantial majority of district courts to consider the issue have held that state-law tort and products liability claims regarding medical devices regulated by the FDA – including Bayer's Essure – do not give rise to federal question jurisdiction. Some have concluded that these state-law claims do not "necessarily raise" federal-law questions. *See, e.g.*, *Sangimino v. Bayer Corp.*, No. 17-cv-01488-WHA, 2017 WL 2500904, at *3 (N.D. Cal. June 9, 2017) (involving Essure); *Vieira v. Mentor Worldwide, LLC*, No. 2:18-cv-06502-AB, 2018 WL 4275998, at *5 (C.D. Cal. Sept. 7, 2018). Others have held that any federal issues that might be "necessarily raised" are not "substantial" or cannot be heard in federal court without disrupting the proper federal-state balance. *See, e.g.*, *Steed v. Bos. Sci. Corp.*, No. 4:17-cv-00824, 2017 WL 2984854,

at *3 (N.D. Ohio July 12, 2017) (collecting cases); *Waitz v. Yoon*, No. 1:14-cv-2875-MHC, 2015 WL 11511577, at *3 (N.D. Ga. June 30, 2015) (collecting cases).

We agree with those courts. As the party seeking removal, Bayer bears the burden of establishing federal jurisdiction, in a context in which we "strictly construe" jurisdictional limits because of the "significant federalism concerns" that attend the removal of cases from state court to federal court. *Mulcahey*, 29 F.3d at 151. We question whether Bayer can establish that the Burrells' state-law claims "necessarily raise" federal-law issues under § 1331. And in any event, Bayer cannot establish that the federal questions it identifies should be heard in federal rather than state court under the third and fourth prongs of the § 1331 analysis.

B.

We start with the requirement that a plaintiff's claims, though brought under state law, "necessarily raise" federal-law questions. As we explain, the theory adopted by the district court – that the Burrells' state-law claims necessarily raise federal preemption questions under § 360k(a) – is not a basis for § 1331 jurisdiction. Whether there might be some other theory on which the Burrells' complaints necessarily raise federal questions is a closer question that we need not decide in this case.

1.

As described above, the district court agreed with Bayer that the "necessarily raised" standard was satisfied here because the Burrells' complaints allege numerous violations of federal regulatory requirements that parallel state-law duties. Under § 360k(a)'s express preemption provision, the court reasoned, the Burrells' right to relief

on their state-law claims turns on whether Bayer breached parallel federal requirements, and so the question of Bayer's compliance with federal law is necessarily implicated by the Burrells' action.

On this point, Bayer and the district court are fundamentally mistaken. A federal question is "necessarily raised" for purposes of § 1331 only if it is a "necessary element of one of the well-pleaded state claims." *Franchise Tax Bd.*, 463 U.S. at 13. It is *not* enough that federal law becomes relevant by virtue of a "defense . . . anticipated in the plaintiff's complaint." *Id.* at 14; *accord Pressl v. Appalachian Power Co.*, 842 F.3d 299, 302 (4th Cir. 2016). As the district court's own reasoning makes clear, that is precisely what is happening in this case: The complaints are "replete" with federal-law references because the Burrells are anticipating a preemption defense by Bayer and explaining how their state-law claims parallel federal standards and thus fall outside § 360k(a)'s express preemption provision. That is not grounds for § 1331 jurisdiction: "[A] case may not be removed to federal court [under § 1331] on the basis of a federal defense, including the defense of preemption, even if the defense is anticipated in the plaintiff's complaint, and even if both parties admit that the defense is the only question truly at issue in the case." *Pinney v. Nokia, Inc.*, 402 F.3d 430, 443 (4th Cir. 2005) (quoting *Franchise Tax Bd.*, 463 U.S. at 14).

We applied exactly that principle in *Pinney*, finding that § 1331 did not confer federal question jurisdiction over state tort and products liability claims regarding a wireless telephone subject to extensive federal regulation. 402 F.3d at 442–49. It did not matter, we held, whether the plaintiffs' state-law claims could be decided without

resolving whether they were preempted by federal law. *Id.* at 446. Under the well-pleaded complaint rule, we explained, our § 1331 inquiry is limited to the plaintiff's statement of his own claim; we do not consider affirmative defenses that might be anticipated in the complaint. *Id.* at 443, 445–46; *see also Flying Pigs, LLC v. RRAJ Franchising, LLC*, 757 F.3d 177, 181 (4th Cir. 2014) ("well-pleaded complaint rule" confines § 1331 inquiry to the "plaintiff's statement of his own claim . . . unaided by anything alleged in anticipation or avoidance of defenses which it is thought the defendant may interpose" (internal quotation marks omitted)). Because the elements of the *Pinney* plaintiffs' state-law claims could be established without resort to federal law, the defendant's preemption defense did not "necessarily" raise a federal-law question cognizable under § 1331: A "lurking question of federal law" in the form of "the affirmative defense of preemption . . . does not make the claims into ones arising under federal law." 402 F.3d at 446.

The same rule applies here. As in *Pinney*, we look only to the necessary elements of the Burrells' causes of action to determine whether they raise federal questions under § 1331. And for most of their theories of liability, it is clear and undisputed that the Burrells can establish all the necessary elements entirely independently of federal law. One example will suffice: In North Carolina, a claim for inadequate warning is made out if "the manufacturer or seller acted unreasonably in failing to provide such warning;" the "failure to provide adequate warning or instruction was a proximate cause of the harm for which damages are sought;" and either "the product, without an adequate warning or instruction, created an unreasonably dangerous condition" or the manufacturer "failed to

take reasonable steps to give adequate warning" after becoming aware "that the product posed a substantial risk of harm to a reasonably foreseeable user." N.C. Gen. Stat. § 99B-5(a). Each of those elements raises purely state-law questions; none requires a showing that Bayer violated federal law. *Cf. Pinney*, 402 F.3d at 446–47 (analyzing elements of plaintiffs' causes of action). Whether Bayer provided FDA-approved warnings may be relevant to Bayer's preemption defense – but, again, "a preemption defense 'that raises a federal question is inadequate to confer federal jurisdiction.'" *Id*. at 446 (quoting *Merrell Dow*, 478 U.S. at 808).[3]

2.

In the face of this clear precedent, Bayer now advances a new rationale for treating the Burrells' state-law action as one that necessarily raises questions of federal law. Among the Burrells' many theories of recovery, Bayer argues, are a few in which violations of federal law are alleged not in anticipation of a preemption defense, but as actual predicates for state-law liability. For one, Bayer emphasizes, the complaints repeatedly assert Bayer's alleged failure to report adverse events to the FDA – a duty

[3] It is well established, of course, that preemption is an affirmative defense. The burden of establishing preemption, in other words, is on the defendant; plaintiffs like the Burrells are not required to establish, nor to allege in their complaints, that their claims are *not* preempted. *Great-W. Life & Annuity Ins. Co. v. Info. Sys. & Networks Corp.*, 523 F.3d 266, 270 (4th Cir. 2008); *see also Metro. Life Ins. Co. v. Taylor*, 481 U.S. 58, 63 (1987) ("Federal pre-emption is ordinarily a . . . defense to the plaintiff's suit. As a defense, it does not appear on the face of a well-pleaded complaint, and, therefore, does not authorize removal to federal court."). To the extent that Bayer or the district court may be understood to suggest the opposite – that non-preemption is somehow an element of the Burrells' state-law causes of action – they are in error.

created solely by federal law, according to Bayer – in connection with multiple causes of action. And both parties focus on the complaints' assertion that Bayer was negligent per se – that is, that Bayer's alleged violations of federal law in and of themselves establish negligence under North Carolina tort law. In instances like these, Bayer urges, a violation of federal law becomes a "necessary element" of the plaintiffs' own state-law claims, satisfying the well-pleaded complaint rule and giving rise to federal question jurisdiction under § 1331.

We may assume for purposes of this appeal that the premise of Bayer's argument is correct, and that the assertions it has identified – including the "fraud on the FDA" allegation – in fact turn on questions of federal law.[4] Even so, there is another hurdle for Bayer: A federal question is not "necessarily" raised under § 1331 unless it is essential to resolving a state-law claim, meaning that "*every* legal theory supporting the claim requires the resolution of a federal issue." *Dixon*, 369 F.3d at 816. If, on the other hand, each of the Burrells' claims is supported by a state-law theory that does not require recourse to federal law, then that claim does not "arise under" federal law – even if the Burrells have alleged an alternative federal-law theory that also could prove liability. *See*

[4] The Burrells acknowledge that their negligence per se theory is predicated on establishing violations of federal law. But it is less clear that the same is true of the "fraud on the FDA" allegation. In *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232–33 (2013) (en banc), the Ninth Circuit considered very similar state-law tort claims predicated on an alleged failure to report adverse events to the FDA, and concluded that the plaintiffs' claims were based on an independent state-law duty to warn that could be satisfied by reports to the FDA, running parallel to the defendant's duties under federal law.

Pressl, 842 F.3d at 304; *Flying Pigs*, 757 F.3d at 182. In other words, so long as "even one theory" for each of the Burrells' claims does *not* require "interpretation of federal law," resolution of the federal-law question is not necessary to the disposition of their case. *Pressl*, 842 F.3d at 304.

According to Bayer, the complaints' allegations of negligence per se and fraud on the FDA should be treated as distinct claims, each requiring resolution of federal-law questions and thus satisfying the "necessarily raised" prong. But the Burrells see it differently, insisting that allegations like negligence per se and fraud on the FDA are merely alternative theories of liability, and that they can recover on each of their actual claims – negligence, products liability, and the like – on an alternative state-law theory that in no way implicates federal law. *See In re Lipitor Antitrust Litig.*, 855 F.3d 126, 144–45 (3d Cir. 2017) (distinguishing between "claims" and "theories" for purposes of "arising under" jurisdiction). For that reason, the Burrells urge, answers to federal-law questions are not essential to any of their claims.

Under the well-pleaded complaint rule, the Burrells are the "master[s] of the[ir] claim," *Pinney*, 402 F.3d at 442 (internal quotation marks omitted), entitled to structure their complaint in the way they think most advantageous. And as the Burrells point out, each of the assertions identified by Bayer is subsumed in their complaints under a cause of action that also includes alternative state-law theories of liability. Faced with a similar complaint in another Essure case, the court in *Sangimino v. Bayer* agreed with the plaintiffs, holding that allegations in their complaint predicated on Bayer's alleged failure to follow FDA requirements were "alternative federal-law-based theories" for state-law

claims that also were "supported by . . . independent" state-law theories. 2017 WL 2500904, at *2 (internal quotation marks omitted). We took a similar approach in *Mulcahey v. Columbia Organic*, treating an allegation of negligence per se based on a violation of federal regulations as "only an alternative theory of liability" under the plaintiffs' negligence cause of action. 29 F.3d at 153. Because the plaintiffs "might still be entitled to recover under an alternative" state-law theory, we held, § 1331 did not confer federal question jurisdiction. *Id.*; *see also In re Lipitor*, 855 F.3d at 147 (rejecting "divide-and-conquer approach to 'arising under' jurisdiction" that would treat alternative theories or factual allegations as separate claims).

At the same time, we think this question is not entirely free from doubt. The distinction between a stand-alone claim and a theory of liability is not always clear. And because that distinction may turn on the precise way in which a complaint is drafted, there is no bright-line rule in the precedent to guide our analysis – nor a prospect that we could provide one through a line-by-line parsing of these particular complaints. Ultimately, we need not decide in this appeal whether the Burrells' complaints assert any distinct claim that can be resolved only by reference to federal law. Instead, for the reasons we turn to now, we conclude that Bayer in any event cannot establish federal question jurisdiction under the third and fourth prongs of the § 1331 analysis.

C.

Under the standard set out by the Supreme Court for identifying the narrow class of state-law actions that will give rise to federal question jurisdiction, it is not enough that a plaintiff's state-law claim necessarily raises some contested federal issue. That federal

issue also must be "substantial," indicating a "serious federal interest" in sending the case to a federal forum; and even if it is, exercising federal jurisdiction must be "consistent with congressional judgment about the sound division of labor between state and federal courts." *Grable*, 545 U.S. at 313. Any doubt on that score is resolved against Bayer, which bears the burden of establishing jurisdiction, especially given the significant federalism implications of removing a state-law action from state court. *See Mulcahey*, 29 F.3d at 148 ("If federal jurisdiction is doubtful, a remand is necessary."). We find that Bayer cannot meet its burden under this part of the § 1331 inquiry.

1.

Our analysis is framed by two Supreme Court cases, one identifying the kind of state-law action that will not give rise to jurisdiction under this standard, and one identifying the kind of action that will. First, in *Merrell Dow v. Thompson*, the Supreme Court held that § 1331 did *not* confer federal question jurisdiction over an action much like this one, in which the plaintiffs alleged state-law products liability claims regarding a pharmaceutical regulated under the FDCA – the same federal statute that governs Essure – and incorporated the federal standard into a cause of action for negligence per se. 478 U.S. at 817. "[T]he mere presence of a federal issue in a state cause of action does not automatically confer federal-question jurisdiction," the Court explained. *Id.* at 813. The Court found it highly significant that Congress had not provided a federal private cause of action for FDCA violations, suggesting a congressional determination that the "presence of the federal issue as an element of the state tort" is "insufficiently 'substantial' to confer federal-question jurisdiction." *Id.* at 814. An alleged "powerful federal interest" in

uniform interpretation of the FDCA, a federal statute, did not change the Court's calculus; a need for uniformity is properly addressed through preemption, not by opening the doors to federal jurisdiction. *Id.* at 815–16.

In the second case, *Grable & Sons v. Darue*, the Supreme Court applied *Merrell Dow* and this time found that a state quiet-title claim *did* present a removable federal question under § 1331, where resolution of the claim depended on the interpretation of a notice standard in federal tax law. 545 U.S. at 314–15. That federal question, the Court held, was "sufficiently real and substantial" because it required establishing the meaning of a federal statute. *Id.* at 316 (internal quotation marks omitted). And importantly, because "it will be the rare state title case that raises" an interpretive question under federal law, removing such cases to federal court "will portend only a microscopic effect on the federal-state division of labor." *Id.* at 315. That was to be contrasted, the Court explained, with the state-law claims at issue in *Merrell Dow*: Because plaintiffs so commonly incorporate an alleged violation of federal standards into "garden variety state tort law" complaints regarding federally regulated products, a "general rule of exercising federal jurisdiction" in those cases would "herald[] a potentially enormous shift of traditionally state cases into federal courts." *Id.* at 318–19.

2.

From those book-end cases – and subsequent Supreme Court decisions applying them – we can derive most of the principles that govern this case. First, as *Grable* makes clear, there is a high bar for treating a federal issue as sufficiently "substantial" under the third prong of the § 1331 analysis. The "classic example," according to *Grable*, is a

federal question regarding the constitutionality or construction of a federal statute, *id.* at 312–13; in *Grable* itself, the question was whether "the action of a federal agency" was "compatib[le] with a federal statute," the resolution of which "would be controlling in numerous other cases," *Empire HealthChoice*, 547 U.S. at 700 (describing *Grable*). As a practical matter, a "substantial" question generally will involve a "pure issue of law," rather than being "fact-bound and situation-specific," *id.* at 700–01, because the crux of what makes a question "substantial" for § 1331 purposes is that it is "importan[t] . . . to the federal system as a whole," and not just to the "particular parties in the immediate suit," *Gunn*, 568 U.S. at 260.

The federal questions implicated by the Burrells' assertions of negligence per se and fraud on the FDA – assuming, as we do, that they are necessarily raised – bear none of these hallmarks of "substantiality." At bottom, what they require are fact-intensive inquiries into Bayer's compliance with certain FDA requirements: whether Bayer timely notified the FDA of alleged adverse events concerning Essure, manufactured Burrell's implant consistent with the FDA-approved design, and properly disseminated FDA-authorized labels and warnings. The Burrells do not allege, by contrast, that the Act is unconstitutional in any of its relevant applications, or that the FDA has exceeded its statutory authority or misapplied its own regulations in its oversight of Essure. Their claims are purely "backward-looking," *id.* at 261, limited to monetary relief for Bayer's alleged past non-compliance with federal safety standards. Though the resolution of those questions undoubtedly is important to Bayer – and to the Burrells – it is not "substantial in the relevant sense," because it lacks "importance more generally" to the

federal regulatory regime and to other medical-device manufacturers. *Id.* at 260–61; *see also Steed*, 2017 WL 2984854, at *4 (remanding state-law action against medical-device manufacturer to state court because the federal issue in the case, while "significant to the parties, . . . does not transcend the parties, affect the government's operations, or challenge federal law in a manner evidencing importance of the issue to the federal system as a whole"); *Patterson v. Bayer Corp. LLC*, No. 6:17-cv-00048-KKC, 2018 WL 1906102, at *3 (E.D. Ky. Apr. 23, 2018) (rejecting Bayer's argument that "applying the federal requirements [at] issue [regarding Essure], particularly reporting requirements, . . . will implicate broader or more substantial federal issues").

Bayer argues, however, that fact-specific questions regarding its federal compliance should be treated as "substantial" in this case because they recur in numerous other cases involving Essure, so that exercising federal jurisdiction would help to ensure uniformity. But the Supreme Court considered and rejected that very argument in *Merrell Dow*, holding that even a strong interest in uniformity of results is not enough to make a federal question "substantial" so that it may be heard in federal court. 478 U.S. at 815–16. State courts are fully capable of resolving federal issues that arise in connection with the state claims before them, and the "possibility that a state court will incorrectly resolve a state claim is not, by itself, enough to trigger the federal courts' . . . jurisdiction, even if the potential error finds its root in a misunderstanding of [federal] law." *Gunn*, 568 U.S. at 263; *see also Merrell Dow*, 478 U.S. at 816 (noting that uniformity concerns are "considerably mitigated" by Supreme Court authority to review decisions of federal issues in state-court actions).

Finally, to the extent Bayer or the district court suggests that the "substantiality" prong is satisfied because the question of federal preemption is a "substantial" one, this is mistaken. It may be true that adjudication of Bayer's federal preemption defense will be important to the outcome of the Burrells' action, and even that the precedent it sets might affect non-parties to this case. But as we have explained already, a federal preemption defense, no matter how substantial, is not grounds for § 1331 jurisdiction. *See Franchise Tax Bd.*, 463 U.S. at 14 (holding that a case may not be removed to federal court on the basis of a preemption defense even where "both parties admit that the defense is the only question truly at issue in the case"). The substantiality inquiry applies only to those federal issues that are necessarily raised by a complaint, and that category does not include affirmative preemption defenses.

3.

Bayer's failure to satisfy the substantiality prong of the § 1331 analysis by itself necessitates a remand to state court. *See Pressl*, 842 F.3d at 303 (§ 1331 confers jurisdiction only "if a case meets all four requirements" of the Supreme Court's four-prong standard (citing *Gunn*, 568 U.S. at 258)). But it follows from the substantiality analysis – and, again, from *Merrell Dow* and *Grable* – that Bayer also cannot make the showing required under the fourth prong: that removal of this state-law case and the multitude of cases just like it would be consistent with the "congressionally approved balance of federal and state judicial responsibilities." *See Grable*, 545 U.S. at 314.

Indeed, the Supreme Court effectively held as much in *Grable*, in the course of explaining why a state quiet-title action, unlike *Merrell Dow*'s state tort action, could be

removed to federal court without upsetting the federal-state judicial balance. Quiet-title actions, the Court observed, only rarely raise substantial questions of federal law, and so they can be removed to federal court when they do without "materially affect[ing] . . . the normal currents of litigation." *Id.* at 319. "Garden variety state tort" actions involving federally regulated products, on the other hand – like *Merrell Dow* and this case – very commonly incorporate allegations of federal regulatory violations, often by way of negligence per se claims. *Id.* at 318. Exercising federal jurisdiction over all of *those* actions, as *Merrell Dow* concluded, would risk enormous disruption to the division of judicial labor, with a "tremendous number of cases" shunted from state to federal court. *Id.* (explaining *Merrell Dow*).

And there is no indication that Congress intended to divert a multitude of fact-intensive, state-law suits against medical-device manufacturers to federal court. Again, *Grable*'s understanding of *Merrell Dow* is controlling. In *Merrell Dow*, the Court explained in *Grable*, the Court relied on two factors to assess Congress's intent with respect to state-law actions involving pharmaceuticals regulated under the FDCA: Congress had not created a private right of action – a direct pathway to federal court – for FDCA violations, and Congress also had not preempted state-law remedies for violations. That combination, the Court concluded, was "an important clue to Congress's conception of the scope of jurisdiction" under § 1331, because it evinced an intent to have such cases

heard by state courts. *Id.* (describing *Merrell Dow*); *see also Merrell Dow*, 478 U.S. at 812.[5]

The same is true here. Like the pharmaceuticals at issue in *Merrell Dow*, Bayer's Essure, a medical device, is regulated under the FDCA. For medical devices, like pharmaceuticals, Congress declined to create a federal cause of action for violations of the Act, while allowing states to "provid[e] a damages remedy for claims premised on a violation of FDA regulations" when those regulations parallel state-law duties. *Riegel*, 552 U.S. at 330. Just as in *Merrell Dow*, it would "flout, or at least undermine" this congressionally-approved enforcement regime, in which injured parties may seek redress under state law and only under state law, to insist that those cases must be heard in federal courts if defendants choose to remove them. 478 U.S. at 812; *see also Grable*, 545 U.S. at 319 ("*Merrell Dow* thought it improbable that the Congress, having made no provision for a federal cause of action, would have meant to welcome any state-law tort

[5] The Court in *Grable* took the opportunity to clarify that *Merrell Dow* does not establish a "bright-line rule" that there can be no jurisdiction in contexts in which Congress has declined to provide a private right of action for enforcement of a federal statute. 545 U.S. at 317. Instead, "*Merrell Dow* should be read in its entirety as treating the absence of a federal private right of action as evidence relevant to, but not dispositive of, the sensitive judgments about congressional intent that § 1331 requires." *Id.* at 318 (internal quotation marks omitted). Adopting Bayer's argument, the district court relied heavily on this doctrinal refinement in its decision, emphasizing that "the fact that there is no private right of action under the FDCA is not dispositive." J.A. 1136. But *Grable* casts no doubt on *Merrell Dow*'s outcome or principal reasoning, and for the reasons given above, *Grable*'s analysis of *Merrell Dow* demonstrates that Bayer cannot establish § 1331 jurisdiction under the final two prongs of the analysis.

case implicating federal law solely because the violation of the federal statute is said to [establish negligence per se] under state law." (internal quotation marks omitted)).

The district court, in concluding otherwise, reasoned that because Congress provided for exacting regulation of medical devices by the FDA and expressly preempted "different" or "addition[al]" state requirements, *see* 21 U.S.C. § 360k(a), the exercise of federal jurisdiction would be consistent with congressional intent. But that conflates the question of preemption with the question of jurisdiction. Congress's desire that a uniform substantive standard apply to FDA-regulated medical devices is a question of preemption law, distinct from congressional intent to vest jurisdiction over such claims in a state or federal forum. *See Merrell Dow*, 478 U.S. at 816. And North Carolina's courts are fully capable of applying federal preemption law, ensuring that the Burrells may recover, consistent with § 360k(a), only for violations of state-law duties that parallel rather than add to Bayer's federal regulatory obligations.

III.

The Burrells' action does not fall within the small class of cases in which state-law claims may be deemed to arise under federal law for purposes of conferring federal jurisdiction under § 1331. Accordingly, the district court erred in denying the Burrells' motion to remand their case to state court and deciding Bayer's motion to dismiss. We therefore vacate the judgments of the district court and remand with instructions that the action be remanded to North Carolina state court.

VACATED AND REMANDED