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IN THE
COURT OF APPEALS OF INDIANA

Bayer Corporation, et al.,
Appellants-Defendants,

v.

Rene Leach, et al.,
Appellees-Plaintiffs.

December 31, 2019

Court of Appeals Case No.
19A-CT-625

Interlocutory Appeal from the
Marion Superior Court

The Honorable James B. Osborn,
Judge

Trial Court Cause No.
49D14-1803-CT-12218

Bailey, Judge.

Case Summary

[1] Rene Leach and more than thirty women (collectively, the "Women") claim they were injured by a medical device called Essure. The Women sued Bayer Corporation and other related entities—the alleged manufacturers of Essure. The complaint contains several legal theories, including alleged manufacturing defects. Certain defendants (collectively, "Bayer") sought judgment on the pleadings, asserting (1) aspects of the complaint are deficient and (2) the claims are preempted. The trial court denied the motion. Bayer now appeals.[1]

[2] Having identified allegations upon which relief could be granted, we affirm.

Discussion and Decision[2]

Standard of Review

[3] A Trial Rule 12(C) motion "tests the sufficiency of a claim or defense presented in the pleadings and should be granted 'only where it is clear from the face of the complaint that under no circumstances could relief be granted.'" *KS&E Sports v. Runnels*, 72 N.E.3d 892, 898 (Ind. 2017) (quoting *Veolia Water Indianapolis, LLC v. Nat'l Trust Ins. Co.*, 3 N.E.3d 1, 5 (Ind. 2014)). Where, as here, the motion "essentially argues the complaint fails to state a claim upon which relief can be granted, we treat it as a 12(B)(6) motion" and engage in *de*

[1] The trial court certified its interlocutory order, and we accepted jurisdiction. *See* Ind. Appellate Rule 14(B).

[2] We held oral argument on December 9, 2019. We thank counsel for their skilled presentations.

novo review. *Id.* Moreover, a complaint states a claim—and, therefore, should not be dismissed—"so long as it states any set of allegations, no matter how unartfully pleaded, upon which the plaintiff could be granted relief." *Graves v. Kovacs*, 990 N.E.2d 972, 976 (Ind. Ct. App. 2013). Under this standard, dismissal is rarely appropriate. *King v. S.B.*, 837 N.E.2d 965, 966 (Ind. 2005).

Adequacy of the Complaint

[4] Trial Rule 8(A) provides that "a pleading must contain . . . a short and plain statement of the claim showing that the pleader is entitled to relief." This "liberal standard merely requires that a 'complaint . . . put the defendant on notice concerning why it is potentially liable and what it stands to lose.'" *KS&E Sports*, 72 N.E.3d at 901 (alteration in original) (quoting *Noblesville Redev. Comm'n v. Noblesville Assocs. Ltd. P'ship*, 674 N.E.2d 558, 564 (Ind. 1996)). In this case, Bayer contends that the Women failed to adequately plead their claims of manufacturing defects. Bayer argues that these claims run afoul of Trial Rule 8 because the Women made "only a cursory effort to describe the manufacturing defects" and their allegations are conclusory. Br. of Appellant at 52. Bayer also asserts that the Women described only potential defects and failed to tie any defect to the alleged injuries. As an example, Bayer directs us to an allegation that a "no lead solder could in fact have trace lead in it." App. Vol. III at 198.

[5] The Women list several potential defects. *See, e.g.*, *id.* at 54 (alleging "the central axis was not fully adhered to the spring which can cause the [device] to

fracture/break apart"). Moreover, the Women allege—plaintiff-by-plaintiff—the emergence of specific symptoms following the implantation of an Essure device. *See, e.g.*, *id.* at 88 ("Plaintiff Jones' post-procedure course has been marked by menorrhagia, extreme fatigue, abdominal pain, back pain, joint pain, and various skin rashes."). Under Indiana's liberal notice-pleading standard, we conclude Bayer has sufficient notice of the defect-related claims. *Cf. Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010) (noting that much of the device-specific manufacturing information is kept confidential by federal law and "[f]ormal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her [defect] claim").[3]

Preemption

Regulatory Background

[6] The Food and Drug Administration (the "FDA") is a federal agency that enforces the Federal Food, Drug and Cosmetic Act (the "FDCA"), *see* 21 U.S.C. ch. 9, including the Medical Device Amendments of 1976 (the "MDA"), *see* Pub. L. No. 94-295, 90 Stat. 539 (codified as amended in scattered sections of 21 U.S.C. ch. 9). In passing the MDA, Congress established a "rigorous regime" of pre-market approval ("PMA") for Class III medical

[3] Bayer alleges the Women failed to adequately plead other claims. However, because we conclude that the manufacturing-defect claims are viable, we need not address any other legal theory.

devices. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). The Women allege that Essure is a Class III medical device that went through the PMA process.

[7] To obtain PMA, a device manufacturer must submit a detailed application. *See* 21 U.S.C. § 360e(c). The FDA grants PMA if it finds "'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360e(d)(1)(A)). In making, selling, and distributing a device, the manufacturer must comply with all applicable federal requirements. *See* 21 U.S.C. §§ 351(h), 352(q). There are generally applicable requirements, including manufacturing standards. *See* 21 U.S.C. § 360j(f)(1)(A); 21 C.F.R. part 820. Moreover, the FDA may impose device-specific requirements—for example, the FDA could require warnings on the label. *See* 21 U.S.C. § 360e(d)(1)(B)(ii). If a medical device is manufactured in violation of applicable federal requirements, the device is deemed adulterated. 21 U.S.C. § 351(h). Further, if a medical device is sold or distributed in violation of its device-specific requirements, the device is deemed misbranded. 21 U.S.C. § 352(q).

[8] Notably, although PMA results in a series of federal requirements, the FDCA itself provides no mechanism for private litigants to sue for non-compliance. Indeed, the FDCA specifies that enforcement proceedings "shall be by and in the name of the United States." 21 U.S.C. § 337(a). Thus, although the federal government regulates medical devices, where—as here—a private litigant alleges injury from a device, the plaintiff must look to state law for a remedy.

[9] There is a "historic primacy of state regulation of matters of health and safety." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). However, because of the Supremacy Clause in Article VI of the U.S. Constitution, courts "must not give effect to state laws that conflict with federal laws." *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 324 (2015). In other words, where state law conflicts with federal law, state law is preempted. *See id.*

Express Preemption

[10] One type of preemption is express preemption—where Congress has included "explicit preemptive text." *State v. Norfolk S. Ry. Co.*, 107 N.E.3d 468, 471 (Ind. 2018). In the MDA, Congress included the following explicit preemptive text:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use **any requirement** . . .
>
> > (1) which is **different from, or in addition to**, **any requirement applicable under this chapter** to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added).[4] With this preemptive text, Congress established a uniform regulatory scheme. *See id.* That is, because different or additional state-law requirements are expressly preempted, manufacturers face only one standard of care—the federal standard of care. *See id.* In other words, Congress established both a regulatory floor and a regulatory ceiling. Through this centralized scheme, Congress prevented states from imposing burdensome regulations that could impede innovation or drive beneficial devices off the market. *See Riegel*, 552 U.S. at 326 (noting that the preemptive text suggests "the solicitude for those injured by FDA-approved devices . . . was overcome in Congress's estimation by solicitude for those who would suffer without new medical devices if juries were allowed to apply the tort law of 50 States").

[11] For example, if the FDA requires monthly reporting and a state requires weekly reporting, the state law is unenforceable because it is expressly preempted. *Cf. Riegel*, 552 U.S. at 330 (noting that the explicit preemptive text precludes claims asserting a violation of state tort law "notwithstanding compliance with the relevant federal requirements"). It follows that a litigant could not predicate a claim on failing to make weekly reports; recovering would be tantamount to enforcing a requirement not found in federal law. *See* 21 U.S.C. § 360k(a).

[12] Thus, due to the explicit preemptive text in the MDA, federal law supplies all germane standards of care. A state may provide a cause of action. However,

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[4] This clause applies unless the FDA grants a specific exception. 21 U.S.C. § 360k(b). Here, there is no indication that a specific exception applies.

any viable state-law claim must be premised on the violation of federal law. In other words, enforceable state requirements—*i.e.*, standards of care—must parallel federal requirements. *See Riegel*, 552 U.S. at 330 (recognizing the viability of parallel claims); *McGookin v. Guidant Corp.*, 942 N.E.2d 831, 838 (Ind. Ct. App. 2011) ("The MDA and *Riegel* could not be clearer that federal law broadly preempts any claim that would allow a jury to impose a standard of care different from or in addition to the FDA's specific federal requirements."); *Bausch*, 630 F.3d at 552 (noting that where state and federal requirements are effectively the same, the state requirements are not expressly preempted).

[13] Turning to the instant case, the Women allege that Bayer violated federal manufacturing requirements. Assuming for now that Indiana law supplies a cause of action, the claim is not expressly preempted because it is premised on a failure to comply with federal requirements. Put differently, the state-law claim avoids express preemption because it is premised on the breach of a duty that the federal government imposed. *See Bausch*, 630 F.3d at 552 (noting that state-law claims "based on violations of federal law are not expressly preempted"); *cf. McGookin*, 942 N.E.2d at 838 (determining claims were expressly preempted where the plaintiffs failed to allege a violation of federal law).

Implied Preemption

[14] Even if a claim is not expressly preempted, however, the claim could be impliedly preempted. *See Norfolk*, 107 N.E.3d at 471. There are two types of implied preemption—field preemption and conflict preemption. *Id.*

Field Preemption

[15] Field preemption applies where Congress intended to exclusively occupy the field. *Id.* Here, the explicit preemptive text leaves room for state-law claims premised on the violation of federal law. *See* 21 U.S.C. § 360k(a) (prohibiting only different or additional state-law requirements). Thus, field preemption does not apply. *See, e.g.*, *Lohr*, 518 U.S. at 485 ("[W]e have long presumed that Congress does not cavalierly pre-empt state-law causes of action.").

Conflict Preemption

[16] "Conflict preemption applies when it is 'physically impossible' to comply with both the state and federal laws" or "when state law does 'major damage' to the federal law's purpose." *KS&E Sports*, 72 N.E.3d at 905 (quoting *Kennedy Tank & Mfg. Co., Inc. v. Emmert Indus. Corp.*, 67 N.E.3d 1025, 1029 (Ind. 2017)). Notably, the existence of preemptive text does not bar the "ordinary working" of conflict-preemption principles. *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869 (2000).

[17] In *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), the U.S. Supreme Court considered whether principles of conflict preemption preclude claims that a device manufacturer defrauded the FDA. The Court examined congressional intent, looking to the statute specifying that proceedings to enforce the FDCA "shall be by and in the name of the United States." 21 U.S.C. § 337(a). From the statute, the Court discerned "clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government." *Buckman*, 531 U.S.

at 352. The Court then disapproved of claims that "exist solely by virtue of the FDCA" while endorsing claims that rely "on traditional state tort law [that] had predated the federal enactments." *Id.* at 353. The Court determined that, where state-law claims exist solely because of the FDCA, allowing the litigation "would exert an extraneous pull on the scheme established by Congress." *Id.* The Court concluded that these types of claims are impliedly preempted. *Id.*

[18] Thus, to avoid both express and implied preemption, first, "the plaintiff must be suing for conduct that *violates* the FDCA (or else [the] claim is expressly preempted by [the explicit preemptive text])." *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010) (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009)). In other words, the plaintiff must allege and prove that the defendant violated an applicable standard set forth in the FDCA. *See* 21 U.S.C. § 360k(a). Second, "the plaintiff must not be suing [solely] *because* the conduct [exclusively] violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Sprint Fidelis Leads*, 623 F.3d at 1204 (quoting *Riley*, 625 F. Supp. 2d at 777). Rather, because only the United States can enforce the FDCA, state law must have recognized an independent duty that now parallels the standard set forth in the FDCA. *See Buckman*, 531 U.S. at 352-53 (interpreting and applying 21 U.S.C. § 337(a)). In short, the plaintiff's claim is not preempted when the plaintiff is enforcing an independent but parallel duty (1) derived from traditional state tort law (2) mirroring a standard imposed by the FDCA. *See id.*

[19] In this case, the Women's claim of manufacturing defects is not expressly preempted because it is premised on the violation of federal requirements. Moreover, the claim is not impliedly preempted so long as it does not exist solely by virtue of the FDCA. That is, the claim survives if the Women are "relying on traditional state tort law." *Id.* at 353.

Manufacturing Defects

[20] The Indiana Product Liability Act ("IPLA") "governs all actions that are: (1) brought by a user or consumer; against a manufacturer or seller; and (3) for physical harm caused by a product; regardless of the substantive legal theory or theories upon which the action is brought." I.C. § 34-20-1-1. Indeed, as our supreme court has explained, it is "clear" the legislature intended that the IPLA govern "all product liability actions, whether the theory of liability is negligence or strict liability in tort." *Stegemoller v. ACandS, Inc.*, 767 N.E.2d 974, 975 (Ind. 2002) (quoting *Dague v. Piper Aircraft Corp.*, 418 N.E.2d 207, 212 (1981)); *see also Vaughn v. Daniels Co. (W. Va.), Inc.*, 841 N.E.2d 1133, 1144 (Ind. 2006). Whether the IPLA governs is a question of law. *Stegemoller*, 767 N.E.2d at 975.

[21] A medical device falls within the IPLA definition of a product. *See* I.C. § 34-6-2-114 (defining "product" as "any item or good that is personalty at the time it is conveyed by the seller to another party" in a transaction not "wholly or predominantly the sale of a service rather than a product"). Moreover, a device manufacturer is a manufacturer or seller under the IPLA. *See* I.C. § 34-6-2-77 (defining "manufacturer" as "a person or an entity who designs, assembles,

fabricates, produces, constructs, or otherwise prepares a product . . . before the sale of the product to a user or consumer"); I.C. § 34-6-2-136 (defining "seller" as "a person engaged in the business of selling or leasing a product for resale, use, or consumption"). Further, the Women allege they each underwent implantation procedures that would make them users or consumers under the IPLA. *See* I.C. § 34-6-2-147 (giving "user" the same meaning as "consumer"); I.C. § 34-6-2-29 (defining "consumer" as "any individual who uses or consumes the product"). Finally, the Women allege they were injured by Essure devices.

[22] We conclude that the claim of manufacturing defects is governed by the IPLA. As to viable claims, the IPLA imposes liability on a manufacturer who

> puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer . . . for physical harm caused by that product to the user or consumer . . . if:
>
> > (1) that user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition;
> >
> > (2) the seller is engaged in the business of selling the product; and
> >
> > (3) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which the product is sold by the person sought to be held liable under [the IPLA].

I.C. § 34-20-2-1.

[23] Here, a jury could reasonably conclude that the alleged failure to comply with federal manufacturing standards rendered Essure in a defective condition unreasonably dangerous to any user or consumer. *See* I.C. § 34-20-2-1. This type of claim is (1) not expressly preempted because it is premised on a violation of federal law and (2) not impliedly preempted because it is derived from traditional Indiana tort law. Thus, the state-law claim is viable.

[24] We find support in *Bausch*. There, the Seventh Circuit addressed whether a manufacturing-defect claim was impliedly preempted when it was premised on the violation of federal manufacturing requirements—conduct that would result in the device being "adulterated" under federal law. *Bausch*, 630 F.3d at 557. The Court determined the claim was not impliedly preempted under *Buckman*:

> While there may not be a "traditional state tort law" claim for an "adulterated" product in so many words, 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. The evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law toward the patient.

Id.

[25] We have concluded that the manufacturing-defect claim is viable. Thus, Bayer has not demonstrated that the complaint is devoid of allegations upon which relief could be granted. *See KS&E Sports*, 72 N.E.3d at 898. Therefore, Bayer is not entitled to dismissal at this early stage of the proceedings.

Other Theories

[26] The Women advance several other legal theories and group their factual allegations based upon those theories. Bayer asserts that some of the allegations involve conduct that is compliant with federal law, and that legal theories based on those allegations would not be viable. However, because a pleading need not identify theories, a court need not strike specific theories upon a motion for judgment on the pleadings. *See Noblesville*, 674 N.E.2d at 564 (explaining that notice pleading requires adequate factual allegations, but not the specification of legal theories); *Graves*, 990 N.E.2d at 976 (noting that a complaint "is sufficient and should not be dismissed so long as it states any set of allegations . . . upon which the plaintiff could be granted relief"); *cf. Bausch*, 630 F.3d at 559 ("When a complaint asserts claims that are legally valid and those that are not, the correct judicial response is not to dismiss the complaint.").

Conclusion

[27] The trial court did not err in declining to enter judgment on the pleadings.

[28] Affirmed.

Baker, J., and Najam, J., concur.