IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

United States Court of Appeals
Fifth Circuit
FILED
January 31, 2012
Lyle W. Cayce
Clerk

No. 11-10076

ALTON BASS,

Plaintiff - Appellant

v.

STRYKER CORPORATION; STRYKER SALES CORPORATION; HOWMEDICA OSTEONICS CORPORATION, doing business as Stryker Orthopaedics,

Defendants - Appellees

Appeal from the United States District Court
for the Northern District of Texas

Before JONES, Chief Judge, HAYNES, Circuit Judge, and CRONE, District Judge.[*]

HAYNES, Circuit Judge:

Plaintiff Alton Bass ("Bass") appeals from the district court's dismissal of his state-law tort claims against Stryker Corporation, Stryker Sales Corporation, and Howmedica Osteonics Corporation, doing business as Stryker Orthopaedics (collectively, "Stryker") pursuant to Federal Rule of Civil Procedure 12(b)(6). In his complaint, Bass alleged that a hip replacement product manufactured by Stryker malfunctioned and caused him injury. Bass argues that the district

[*] United States District Judge for the Eastern District of Texas, sitting by designation.

court erred in concluding that *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), forecloses his state-law claims because: (1) the Trident PSL Acetabular Shell (or "Shell") manufactured by Stryker was not subject to pre-market approval ("PMA") testing and therefore *Riegel* is inapplicable; and (2) even if *Riegel* is applicable, his state-law claims merely "parallel" the federal requirements and therefore are expressly allowed under *Riegel*. Bass also challenges the district court's holding that his claims, even if parallel, are impliedly preempted by 21 U.S.C. § 337(a). For the reasons that follow, we AFFIRM the dismissal of Bass's strict liability, design defect, negligence, and Texas Deceptive Trade Practices Act ("DTPA") claims to the extent they are premised on a failure to warn or a marketing defect; AFFIRM as to Bass's breach of express warranty claims; and REVERSE and REMAND the following: (1) Bass's strict liability and negligence claims, to the extent they are based on manufacturing defects that violate the Food and Drug Administration's ("FDA") Current Good Manufacturing Practices ("CGMPs") or are inconsistent with Stryker's manufacturing processes or procedures that were approved by the FDA; (2) his claim for breach of an implied warranty to the extent it relies on the failure to comply with the FDA's requirements; and (3) his DTPA claim, to the extent that it relies on a breach of an implied warranty.

I. FACTS AND PROCEDURAL HISTORY

Alton Bass underwent left hip replacement surgery in August 2007. As a part of the surgery, the surgeon implanted a hip replacement consisting of four components, each manufactured by Stryker: (1) a Shell; (2) an Accolade TMZ Plus Hip Stem #4.5; (3) a V40 Alumina Femoral Head; and (4) a Trident 0 Alumina Insert. Following the hip replacement, Bass allegedly began to experience pain in his left hip, despite following all of his surgeon's instructions

after surgery. For the next two years, Bass complained to his surgeon about increasing pain in his left hip. Bass then underwent a revision of his hip replacement. The surgeon determined that the Shell was too loose and revised it. Bass alleges that the looseness was caused by manufacturing residuals on the Shell which prevented bony ingrowth to the Shell.

On October 23, 2009, Bass filed suit against Stryker in the Northern District of Texas, asserting diversity jurisdiction. Bass raised a number of state-law claims, including strict liability, negligence, breach of warranty, and violation of the DTPA. Stryker filed a motion to dismiss, claiming that Bass's state-law claims were preempted by the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetics Act ("FDCA"), *see* 21 U.S.C. § 360c *et seq.*, and by 21 U.S.C. § 337(a). The district court granted Stryker's motion to dismiss on preemption grounds. Bass filed a timely notice of appeal.

II. STANDARD OF REVIEW

This court reviews the district court's grant of a motion to dismiss de novo. *Wampler v. Sw. Bell Tel. Co.*, 597 F.3d 741, 744 (5th Cir. 2010). All well-pleaded facts in the complaint are accepted as true and viewed in the light most favorable to the nonmovant. *Jebaco Inc. v. Harrah's Operating Co.*, 587 F.3d 314, 318 (5th Cir. 2009). Dismissal is appropriate when the plaintiff has not alleged enough facts to state a claim to relief that is plausible on its face or has failed to raise his right to relief above the speculative level. *Wampler*, 597 F.3d at 744.

III. DISCUSSION

A. Whether the district court erred in finding that the Shell was subject to PMA testing.

Before addressing Bass's first argument, we provide a brief overview of the statutory scheme applicable to medical devices. In response to the concern that state-law governance of medical devices was inadequate, Congress passed the

MDA, giving the FDA authority to regulate medical devices and expressly preempting certain state regulations. *See Riegel*, 552 U.S. at 315-16; *see also* 21 U.S.C. § 360k.

The devices at issue in this litigation are Class III devices, which receive the most federal oversight. *Riegel*, 552 U.S. at 317; *see also Funk v. Stryker Corp.*, 631 F.3d 777, 779 (5th Cir. 2011) ("Trident is a Class III device under the [FDCA]."). Most Class III devices are approved by a review determining that the device is "substantially equivalent" to another device exempt from the PMA process. *See Riegel*, 552 U.S. at 317. This is referred to as a § 510(k) approval. *Id.* The remaining devices are approved through the "rigorous" PMA process. *Id.*

A state-law tort claim to recover for injuries allegedly caused by a medical device is preempted if: (1) "the Federal Government has established requirements applicable to [the device]"; and (2) the claims are based on state-law requirements that are "'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22 (quoting 21 U.S.C. § 360k(a)(1)). Devices that are approved through PMA procedures automatically satisfy the "federal requirements" prong. *Id.* at 322 ("Premarket approval . . . imposes 'requirements' under the MDA as we interpreted it in [*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)]."). In contrast, the § 510(k) approval process does not impose federal requirements on a device. *See Lohr*, 518 U.S. at 493-94 ("[E]ven though the FDA may well examine § 510(k) applications for Class III devices . . . with a concern for the safety and effectiveness of the device, . . . it did not 'require' Medtronics' pacemaker to take any particular form for any particular reason." (internal citation omitted)).

Bass argues that the district court wrongfully concluded that the Shell, which malfunctioned, was subject to PMA testing. He argues that: (1) the

district court was required to credit his allegation that the FDA had not granted PMA approval to the Shell as true; and (2) even if the district court was not required to accept the truth of his pleading, the district court nonetheless erred in determining that the FDA documents indicate that the FDA considered the Shell to be a part of the Trident hip replacement system. We address both arguments in turn.

1. Whether the district court erred by failing to accept Bass's allegation that the Shell was not subject to PMA testing.

The district court's decision that the Shell was subject to PMA testing was based upon publicly available documents from the FDA. Although a district court ruling on a motion to dismiss is required to accept all well-pleaded facts as true, "courts 'are not bound to accept as true a legal conclusion couched as a factual allegation.'" *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (quoting *Papasan v. Allain*, 478 U.S. 265, 286 (1986)).

We conclude that the determination of whether the Shell was subject to the PMA process is a question of law. We have held that where underlying facts are not disputed, the significance of those facts becomes a question of law. *See, e.g.*, *House v. Am. United Life Ins. Co.*, 499 F.3d 443, 448 (5th Cir. 2007) ("We have frequently stated that the existence of an ERISA plan within the statutory definition is a question of fact. . . . However, where the factual circumstances are established as a matter of law or undisputed, we have treated the question as one of law to be reviewed *de novo*."); *AT&T Corp. v. PUC*, 373 F.3d 641, 645 (5th Cir. 2004) ("The material facts in this case are not in dispute, therefore we review *de novo* the district court's preemption decision and the interpretation of the TA96."). Bass does not dispute that testing was done or that the documents describing the FDA's approval process are subject to judicial notice; rather, Bass's allegation asks the court to make a conclusion as to the legal significance of these tests and the FDA's subsequent approval of the Trident system.

Therefore, we treat Bass's allegations that the Shell did not receive PMA testing as a legal conclusion that the district court was not required to accept as true.

2. Whether the district court erred in concluding that the FDA documents showed that the Shell was approved through the PMA process.

Bass alleges that the district court erroneously concluded that the Shell was subject to PMA testing. Bass points to statements made at the FDA public hearing in which a Stryker employee indicated that "only the ceramic inserts are under investigation in these systems." *See* Medical Devices Advisory Committee, Summary Minutes of the Orthopedic and Rehabilitation Devices Panel, at 12 (July 20, 2000), *available at* http://www.fda.gov/ohrms/dockets/ac/00/minutes/3633m1.pdf. However, as Stryker points out, at the same meeting, the FDA Director of General and Restorative Devices "clarified for the panel that they would be voting on an entire system and not just the ceramic on ceramic interface." *Id.* at 16.[1]

Additionally, there are numerous indications that the FDA considered the Shell to be a part of the Trident system. Perhaps most significantly, the PMA supplements included in the record indicate that changes to the labeling and design of the Shell were approved through the PMA process. Supplemental approval of changes is required for any device which has received PMA approval.

[1] Other courts have also concluded at the motion to dismiss stage that the Shells were subject to the PMA process. *See Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 657 (S.D. Tex. 2010) ("[T]hat the acetabular shell was previously approved through only the § 510(k) process . . . does not change the fact that it was later subject to the more rigorous scrutiny of the PMA process as a component of the Trident System."); *see also Cornwell v. Stryker Corp.*, No. 1:10-cv-00066, 2010 U.S. Dist. LEXIS 116824, at *8 (D. Idaho Nov. 1, 2010); *Phillips v. Stryker Corp.*, No. 3:09-CV-488, 2010 U.S. Dist. LEXIS 55117, at *14-15 (E.D. Tenn. June 3, 2010); *Delaney v. Stryker Orthopaedics*, No. 08-03210, 2009 U.S. Dist. LEXIS 16865, at *10 (D.N.J. Mar. 5, 2009) ("[Plaintiff] further argues that discovery is needed to determine if all or only part of the Trident TM was subject to the PMA process. Discovery is not required in this instance because [Stryker] has sufficiently demonstrated that the Trident TM underwent the PMA process.").

See Lewkut, 724 F. Supp. 2d at 655 ("[S]everal supplements approved by the FDA through the PMA process after the Trident System's initial approval refer to the acetabular shell component in a manner that strongly suggests that it had already been approved."); *Purcel v. Advanced Bionics Corp.*, No. 3:07-cv-1777, 2010 U.S. Dist. LEXIS 67109, at *8-9 (N.D. Tex. June 30, 2010) ("Supplemental premarket approval is evaluated largely by the same procedures, criteria, and extensive scrutiny as the original PMA process."). Furthermore, the record also indicates that the safety and effectiveness data for the PMA testing refers to the Shell as a component of the system. For these reasons, we hold that the district court did not err in determining that the Shell in its entirety was subject to PMA approval and therefore satisfied the "federal requirement" prong of *Riegel*.

B. Whether the district court erred in determining that Bass's complaint failed to plead parallel claims.

We now turn to the preemption question. Although "common-law causes of action for negligence and strict liability do impose 'requirement[s],'" *Riegel*, 552 U.S. at 323-24; *see also id*. at 324 ("Absent other indication, reference to a State's 'requirements' includes its common-law duties."), that is not the end of our inquiry. "[Section] 360k does not 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.

The district court determined that Bass's claims do not parallel FDA requirements.[2] Two subsequent opinions from our court—*Funk*, 631 F.3d 777,

[2] Although neither party discusses this in its brief, parts of the district court's order dismissing the suit appear to be premised upon Bass's original complaint rather than the amended complaint. To the extent that the district court relied on the original complaint, such reliance was error. The amendment was filed before Stryker filed a responsive motion, and therefore no leave of the district court was required. *See* FED. R. CIV. P. 15; *see also Santee v. Quinlan*, 115 F.3d 355, 357 (5th Cir. 1997). Because the complaint was amended as of right, our analysis proceeds as to the Amended Complaint.

and *Hughes v. Boston Scientific Corp.*, 631 F.3d 762 (5th Cir. 2011)—compel an opposite conclusion as to some of his claims.

In *Funk*, we dealt with a nearly identical claim that the Shell failed to attach correctly due to impurities in the manufacturing process. 631 F.3d at 782. In that case, we recognized that such an injury could lead to a parallel claim but held that the plaintiff's pleadings were too conclusory to state a claim. *See id.* ("[Funk's] claim that Stryker violated FDA manufacturing requirements when producing Trident was not legally cognizable as set out in his pleadings before the district court. . . . This complaint is impermissibly conclusory and vague."). Specifically, Funk's complaint did

> not specify the manufacturing defect; nor d[id] it specify a causal connection between the failure of the specific manufacturing process and the specific defect in the process that caused the personal injury. Nor d[id] the complaint tell us how the manufacturing process failed, or how it deviated from the FDA approved manufacturing process.

Id. This conclusion was consistent with a number of other courts holding that to plead a parallel claim successfully, a plaintiff's allegations that the manufacturer violated FDA regulations must meet the *Twombly* plausibility standard. *See, e.g.*, *In re Medtronic Inc.*, 623 F.3d 1200, 1203 (8th Cir. 2010); *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 280 (E.D.N.Y. 2009); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008); *cf. Bausch v. Stryker Corp.*, 630 F.3d 546, 558, 560 (7th Cir. 2010) (acknowledging that *Twombly* applies, but rejecting the notion that *Twombly* requires the plaintiff to allege which specific regulation was violated).

In *Hughes*, we noted that any claim asserting a state-law tort action despite compliance with FDA regulations was preempted by the MDA. 631 F.3d at 768. However, state common law claims "are not preempted, provided that such claims are premised entirely on violation of the applicable federal

requirements." *Id.* at 770. Importantly, a formal finding of a violation by the FDA was not required to plead a parallel action. *See id.* at 772 ("We are persuaded that any additional 'formal' finding or enforcement action by the FDA is not an 'implicit precondition' to suit under the facts of this case."). We ultimately held that the cause of action survived where the plaintiff provided expert testimony showing that the medical device manufacturer had "violated the plain text of the [Medical Device Reporting] regulations." *Id.* at 773.

Under *Funk* and *Hughes*, Bass has sufficiently pleaded parallel claims in his first amended complaint, to the extent that the claims are based upon manufacturing defects resulting from violations of federal regulations. Bass alleges that his injury was caused by the Shell's failure to attach to the bone. The complaint further alleges that the Shell was adulterated due to violations of 21 C.F.R. §§ 820.20(a), 820.20(b)(2), and 820.70(e). In support of the allegations that the Shell was adulterated, Bass pleaded that Stryker initiated a recall on its Shell, and that the recall "included Plaintiff's specific hip device." Bass also alleged that the FDA sent a warning letter to Stryker five months before his surgery, which included a notice that Stryker failed to verify and implement changes to reduce the Final Rinse Tank bioburden. *See* Letter from Timothy A. Ulatowski, Director, FDA Office of Compliance to Michael McGrath, General Manager/Vice President, Stryker Ireland (Mar. 15, 2007), http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2007/ucm076326.htm [hereinafter Warning Letter]. According to Bass, the recall followed an investigation in which the FDA noted that manufacturing residuals in excess of those permitted by the FDA were found on the Shells and that the Shells were "adulterated within the meaning of section . . . 21 U.S.C. § 351(h)." Warning Letter at 1. Bass also pleaded that excess bioburden (microbial contaminant) and manufacturing residuals on the Shells are known to prevent bony ingrowth,

resulting in a loose cup, which is the injury that Bass pleads. In summary, Bass pleaded: (1) he received a Shell implant; (2) the FDA had previously warned Stryker of bioburden in excess of FDA regulations in its final rinse of the Shells; (3) after Bass's surgery, Stryker ultimately voluntarily recalled those Shells, including the Shell specifically used in Bass's implant; (4) Bass suffered from a loose Shell due to a lack of bony ingrowth; and (5) the lack of bony ingrowth is a known effect of an excess of bioburden and manufacturing residuals on Shells. Bass has thus pleaded sufficient facts to find that his injury plausibly resulted from a violation of FDA standards in connection with his manufacturing defect claims, as more fully explained below, and, therefore, has pleaded a non-conclusory parallel claim under our precedents in *Funk* and *Hughes*.

Stryker argues that Bass "does not plead that his doctor saw any signs of contamination on the device when it was removed or that the Plaintiff had an infection at the sight of the hip replacement." Stryker argues that Bass's claim is essentially one of *res ipsa loquitur*, which we rejected in *Funk*. *See* 631 F.3d at 782. However, Bass's pleadings are more detailed than those in *Funk*. *See id*. Unlike the *Funk* complaint, Bass "specifies with particularity what went wrong in the manufacturing process and cites the relevant FDA manufacturing standards Stryker allegedly violated." *Id*. Evidence that the doctor noticed contamination on the Shell would provide evidentiary support for a finding of contamination, but Stryker does not point to any case stating that such allegations are required at the motion to dismiss stage. We conclude that these pleadings are sufficient as to Bass's specific injury.

Similarly, we conclude that Bass has pleaded sufficient facts as to Stryker's failure to conform with FDA regulations in manufacturing the Shell. As noted above, Bass pleads that the FDA warned Stryker of excess contaminant in the manufacture of its Shells; that the Shells, including the Shell implanted

into Bass's hip, were ultimately recalled because of contamination issues; and that Bass's Shell caused the type of injury that is consistent with excess contamination. These allegations plausibly contend that Stryker's manufacturing of the Shells failed to conform to FDA regulations and rendered them defective.

Stryker also argues that even if Bass's allegations are not conclusory, they nonetheless fail to allege adequately that Stryker did not comply with FDA regulations. In support of this argument, Stryker notes that the recall of the Shells was voluntary, that the pleadings regarding the Warning Letter are conclusory, and that the Warning Letter "is not a final determination of an FDA decision." Stryker also notes that at all times the Trident system maintained its PMA approval.

However, this claim is undermined by our decision in *Hughes*. The manufacturer in *Hughes* similarly argued that "the FDA never made a 'formal' finding that [the manufacturer] failed to comply with the MDR regulations or initiated an enforcement action against [it.]" 631 F.3d at 772. We rejected the argument that a formal finding of a violation or an enforcement action was a necessary precursor of a parallel claim. *Id*. at 772-73. The device in that case similarly had PMA approval, *id*. at 764, and nothing in the opinion suggests that the approval was revoked; rather, the fact that we acknowledged that the FDA had not taken any enforcement action likely precludes the possibility that the PMA approval had been revoked.

Additionally, although the Warning Letter itself is somewhat unclear, it does identify that the Trident Acetabular System was determined by the FDA to be "adulterated within the meaning of section 501(h) of the [FDCA]." Warning Letter at 1. The letter also mentions that the FDA had found "Final Rinse Tank bioburden nonconformances" and notes that Stryker's response to some of these

"nonconformances" was inadequate. *Id*. at 3. Therefore, the letter appears to provide further support for Bass's allegations. Furthermore, as the Seventh Circuit noted, and as the redactions in the Warning Letter illustrate, "courts must keep in mind that much of the product-specific information about manufacturing needed to investigate [a medical device claim] fully is kept confidential by federal law." *Bausch*, 630 F.3d at 558. Therefore, asking the plaintiff to make more specific allegations than those found in Bass's complaint may make pleading a parallel claim regarding defective manufacturing nearly impossible. *See In re Medtronic*, 623 F.3d at 1209 (Melloy, J., dissenting) (stating that *Twombly* only requires a degree of specificity that may be achieved without the use of confidential documents). At this early stage, Bass has successfully alleged that Stryker's manufacturing was conducted in violation of the applicable federally mandated standards and resulted in the contamination of some of the Shells, including the Shells at issue.

Finally, Stryker argues that we should affirm the district court's opinion because the regulations upon which Bass relies are CGMPs, which are "not specific enough to constitute parallel claims." This contention is not that the *allegations* are not specific enough to plead a claim, but rather that the *regulations* are not specific enough to support a claim.

Although the circuits are not in complete agreement as to what constitutes a sufficient pleading with regard to a CGMP, the pleadings here would satisfy any of the courts relied upon by Stryker. The key distinction between complaints that are sufficient to withstand a motion to dismiss and those that are not is not reliance on CGMPs, but rather the existence of a manufacturing defect caused by a violation of federal regulations *and* allegations connecting a defect in the manufacture of the specific device to that plaintiff's specific injury. *See Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011)

(affirming summary judgment but stating that a complaint is adequate if it "set[s] forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged" (internal quotation marks omitted)); *In re Medtronic*, 623 F.3d at 1207 (noting that a plaintiff must plead that the manufacturer "violated a federal requirement specific to the FDA's PMA approval of th[e] Class III device" and concluding that classwide claims of generic manufacturing defects do not survive a motion to dismiss); *Bausch*, 630 F.3d at 555-56 (concluding that violations of CGMPs are not too general to be applied by a jury). This is perhaps best summed up in *In re Medtronic*, in which the Eighth Circuit noted that reliance on CGMPs may be appropriate where, as here, "a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the PMA prior to commencing the lawsuit." *In re Medtronic*, 623 F.3d at 1206.

Here, Stryker alleges that permitting Bass to proceed would allow a jury to set bioburden or residual standards that are not in the regulations. Bass responds that the FDA approves the manufacturing process in the PMA application, *see Riegel*, 552 U.S. at 317-18, such that the jury could measure Stryker's performance against this specific FDA-approved PMA process.

In *Riegel*, the Supreme Court noted that "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323. The PMA application that is approved by the FDA is more specific than the regulations. *Cf. id.* at 318 (noting that PMA application "includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a 'full statement' of the device's

'components, ingredients, and properties and of the principle or principles of operation'; 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device'; samples or device components required by the FDA; and a specimen of the proposed labeling" (quoting 21 U.S.C. § 360e(c)(1)).

Thus, we cannot agree that the regulations are too vague to be enforced by a jury, because by the time the case is tried, the jury will have before it the PMA application that was approved by the FDA. To the extent a plaintiff can show that the FDA-approved processes and procedures were not followed, and that the injury was caused by this deviation, the plaintiff's claim will be parallel. However, if the plaintiff challenges the suitability of the precise processes or procedures chosen by the maker, and approved by the FDA, to achieve the broader regulatory goals, such a claim could not proceed.

We therefore hold that if a plaintiff pleads that a manufacturer of a Class III medical device failed to comply with either the specific processes and procedures that were approved by the FDA or the CGMPs themselves *and* that this failure caused the injury, the plaintiff will have pleaded a parallel claim. To illustrate, suppose a manufacturer had represented to the FDA in its pre-approval documentation that each hip implant component would be sterilized for ten minutes at 800 degrees. We would accept a parallel claim that pleaded that the manufacturer instead sterilized the component at only 200 degrees for five minutes, as that would "violate" what it told the FDA. However, if the plaintiff's claim was that proper sterilization required twenty minutes at 1000 degrees or some other method of sterilization altogether, this claim would not be allowed, as it would "add to" the regulatory requirements. Thus, we reject Stryker's argument that the regulations are too vague to be enforced because

Bass will have to prove violations of the more specific, FDA-approved PMA process for this device.

Furthermore, we have already rejected a similar argument in *Hughes*. In that case, the manufacturer argued that "permitting [a] jury to determine whether [it] violated the FDA's reporting requirements would lead to the possible imposition of different or additional state requirements." 631 F.3d at 772. We noted that "any danger that the jury in th[at] case may apply the plain terms of the MDR regulations in a different or more stringent manner than the FDA intended is considerably mitigated by the summary judgment evidence indicating that the FDA disapproved of [the manufacturer's] reporting practices." *Id*. at 773; *see also id.* at 774 ("This evidence strongly suggests that the FDA concluded that [the manufacturer's] algorithm failed to satisfy the MDR regulations requiring reports of 'serious injuries.'").

Under these standards, Bass sufficiently alleged a concrete injury and a connection between a defect in Stryker's manufacture of the Shells and Bass's injury. Notably, unlike the plaintiffs in *In re Medtronic* and *Wolicki-Gables*, Bass does not allege that his injury simply arises from Stryker's failure to abide by the CGMPs, but rather alleges that the failure to abide by its own manufacturing standards required to satisfy the CGMPs and the PMA approval process resulted in an unacceptable level of bioburden on his Shell. *See* Warning Letter at 3 (noting Final Rinse Tank nonconformances). Furthermore, the FDA itself determined that Stryker was in violation of the CGMPs. *See* Warning Letter at 1 ("[The FDA's] inspection revealed that . . . the methods used in, or the facilities or controls used for, [the] manufacture, packing, storage, or installation [of the Shells] are not in conformity with the [CGMP] requirements of the Quality System (QS) regulation found at [21 C.F.R. 820]."). The fact that the FDA was able to determine, even preliminarily, that Stryker violated the manufacturing (or sterilization) procedures that it adopted to fulfill the CGMPs

suggests that the federal regulations are not so vague that they "[do] not spell out standards that the court could enforce." Therefore, we hold that Bass's reliance, in part, on CGMPs does not preclude him from having effectively alleged a parallel claim.

C. Whether the district court erred in holding that Bass's claims are preempted under § 337(a).

The district court held that even if Bass's claims are not preempted by § 360k, they are preempted by 21 U.S.C. § 337(a), which provides that "all such proceedings for the enforcement, or to restrain violations, of this Act . . . shall be by and in the name of the United States." 21 U.S.C. § 337(a). The district court then held that under the workings of § 360k and § 337(a), a state-law claim for injuries sustained from a PMA-tested medical device will only be valid in the face of a statute creating causes of action for violations of the FDCA.

We considered and rejected this interpretation of *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), in *Hughes*. There, we noted that there is a difference between the "freestanding federal cause of action based on violation of the FDA's regulations" presented by the plaintiffs in *Buckman* and a state-law tort claim. *See* 631 F.3d at 775; *see also Bausch*, 630 F.3d at 558 (distinguishing between a "breach of a recognized state-law duty" and "an implied right of action under federal law"). "*Riegel*, decided long after *Buckman* . . . unequivocally held that parallel state claims survive a defendant's preemption defense under the MDA . . . ." *Hughes*, 631 F.3d at 775. This case is premised on state-law tort claims rather than any duties independently created by FDA regulations.

Stryker argues that *Hughes* is distinguishable because it is based on Mississippi law, which could allow a plaintiff to show that a defendant violated its duty of care by proving a federal regulatory violation. Stryker asserts that under Texas law, "statutory and regulatory violations do not establish a violation

of the state standard of care unless negligence per se applies." It contends that even if Bass pleaded negligence per se, Texas would not permit a showing of negligence per se based on FDCA violations.

We reject Stryker's attempt to distinguish *Hughes* on this basis; even if Stryker is correct that Bass may not rely on the theory of negligence per se, he may still have a negligence cause of action. Indeed, as noted by the Texas Supreme Court, "[n]egligence per se is a tort concept whereby a legislatively imposed standard of conduct is adopted by the civil courts as defining the conduct of a reasonably prudent person." *Carter v. William Sommerville & Son, Inc.*, 584 S.W.2d 274, 278 (Tex. 1979). "In such a case the jury is not asked to judge whether or not the defendant acted as a reasonably prudent person would have acted under the same or similar circumstances; the statute itself states what a reasonably prudent person would have done." *Id.* Even though Bass may not be able to rely on the theory of negligence per se to establish a violation of the standard of care, Bass has sufficiently alleged facts, which, if true, would support a claim that Stryker was negligent.

Indeed, it is evident from the Texas Supreme Court's discussion in *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998), that it would not disallow tort claims predicated on violations of FDA regulations. *Id.* at 372-77. *Purcel* also indicated that 21 U.S.C. § 337(a) did not preempt negligence and products liability causes of action under Texas law. *See* 2010 U.S. Dist. LEXIS 67109, at *20-21. Yet another court concluded that "claims based on a manufacturer's failure to follow the FDA's regulations and procedures in manufacturing and marketing a device are not preempted." *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127, 138 (Tex. App.—Houston [1st Dist.] 2005, pet. denied). We therefore conclude that Bass's parallel state claims are not preempted by 21 U.S.C. § 337(a).

D. Which claims survive?

Based on the above analysis, we conclude that the only claims that survive preemption are manufacturing defect claims premised on Stryker's alleged violations of the FDA regulations and requirements.

1. Strict Liability

To plead a cause of action for strict liability under Texas law, Bass must plead that: (1) Stryker placed the Shells in the stream of commerce; (2) the Shells were in a defective or unreasonably dangerous condition; (3) there was a causal connection between the defect and his injury; and (4) the Shell was expected to and did reach him without substantial change in the condition in which it is sold. *See Hous. Lighting & Power Co. v. Reynolds*, 765 S.W.2d 784, 785 (Tex. 1988). Bass pleads two kinds of claims for strict liability: a manufacturing defect and a "marketing defect." Bass's manufacturing defect claims may proceed, because, as discussed above, to the extent they are premised on violations of FDA regulations, they are parallel claims that are not preempted. *See Purcel*, 2010 U.S. Dist. LEXIS 67109, at *34. However, to the extent that Bass's claims are premised on a "marketing defect," Bass has not pleaded specific facts as to how the marketing of the Trident system violated FDA regulations; therefore, we affirm the district court's dismissal of those claims. *See In re Medtronic*, 623 F.3d at 1205 ("The FDA's PMA approval includes specific language for Class III device labels and warnings. Plaintiffs did not allege that Medtronic modified or failed to include FDA-approved warnings."); *Purcel*, 2010 U.S. Dist. LEXIS 67109, at *20 ("Plaintiffs cite no federal requirement obligating [the manufacturer] to warn them that the devices were adulterated. These claims of . . . failure to warn impose a requirement in addition to those approved by the FDA—the duty to warn consumers if devices are adulterated—and are therefore preempted by § 360k(a).").

2. Negligence

For the same reasons that the strict liability "marketing defect" claim is dismissed, we affirm the district court's dismissal of Bass's claims for negligence to the extent that they are premised on a failure to warn or improper marketing. Bass did not plead that Stryker failed to include FDA-approved warnings, and any claim that Stryker had a duty to warn consumers that the Shell was adulterated is preempted by § 360k(a). *Purcel*, 2010 U.S. Dist. LEXIS 67109, at *20.

However, as discussed in detail above, Bass's negligent manufacturing claims survive, as they are parallel claims that do not impose different or additional requirements than the FDA regulations because Bass pleaded that Stryker failed to abide by the FDA regulations in the manufacture of the Shell. *Hughes*, 631 F.3d at 775-76; *Purcel*, 2010 U.S. Dist. LEXIS 67109, at *12. Even if Bass cannot rely on the theory of negligence per se to prove his case, Texas law does allow "parallel" negligent manufacturing claims to proceed. *E.g.*, *Schronk v. City of Burleson*, No. 10-07-00399-CV, 2009 Tex. App. LEXIS 5654, at *68 (Tex. App.—Waco July 22, 2009, pet. filed) (allowing a claim that a medical device was "defectively manufactured, designed, supplied, sold, or marketed to the City" to go forward); *Purcel*, 2010 U.S. Dist. LEXIS 67109, at *34 (allowing plaintiff's negligent manufacturing claims to proceed under Texas law). Therefore, we hold that the district court erred in dismissing Bass's negligent manufacturing claims.

3. Express Warranty

We agree with *Medtronic* that the express warranty claims cannot be used to impose requirements greater than that provided by the FDA regulations. *Medtronic*, 623 F.3d at 1207. To the extent that Bass is claiming that Stryker made some affirmative representation of compliance with FDA manufacturing

processes, he has done so only in a wholly conclusory fashion. Therefore, we affirm the dismissal of Bass's express warranty claim. *See, e.g.*, *Purcel*, 2010 U.S. Dist. LEXIS 67109, at *37; *Delaney*, 2009 U.S. Dist. LEXIS 16865, at *16.

4. Implied Warranties

To prevail on a breach of the implied warranty of merchantability, a plaintiff must prove that: (1) "the defendant sold or leased the product to the plaintiff; (2) the product was unmerchantable; (3) the plaintiff notified the defendant of the breach; and (4) the plaintiff suffered injury." *Purcel*, 2010 U.S. Dist. LEXIS 67109, at *23; *see also* TEX. BUS. & COM. CODE ANN. § 2.314 (West 2009). A product is unmerchantable if it is "unfit for its ordinary purpose." *Purcel*, 2010 U.S. Dist. LEXIS 37109, at *23.

"To establish a breach of the implied warranty of fitness for a particular purpose, the plaintiff must establish that (1) the seller had reason to know any particular purpose for which the goods were required at the time of contracting and (2) the buyer was relying on the seller's skill or judgment to select or furnish suitable goods." *Hartford v. Lyndon-DFS Warranty Servs., Inc.*, No. 01-08-00398-CV, 2010 Tex. App. LEXIS 4241, at *28-29 (Tex. App.—Houston [1st Dist.] May 28, 2010, no pet.); *see also* TEX. BUS. & COM. CODE ANN. § 2.315 (West 2009).

Some courts that have considered this issue have concluded that implied warranty claims are preempted because a finding that a product is unmerchantable or unfit for the purpose for which it is intended conflicts with the PMA process, through which the FDA has explicitly approved the device. *See Michael v. Shiley*, 46 F.3d 1316, 1325 (3d Cir. 1995); *King v. Collagen Corp.*, 983 F.2d 1130, 1135-36 (1st Cir. 1993). However, both *Michael* and *King* were decided before the Supreme Court's decisions in *Lohr* and *Riegel*. In *Riegel*, the Supreme Court affirmed the dismissal of the plaintiff's negligence, strict

liability, and implied warranty claims, but noted that this was because the district court "interpreted the claims [in that case] to assert that Medtronic's device violated state tort law notwithstanding compliance with the relevant federal requirements . . . ." 552 U.S. at 330. The Court explicitly stated that "§ 360k does not 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.*

Several courts that have addressed whether implied warranty claims are preempted after *Riegel* have determined that, to the extent the plaintiff relies on the failure to comply with the FDA's requirements in asserting its breach of implied warranty claim, such claims may proceed. *E.g., Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830, 839-40 (S.D. Ind. 2009) (concluding that an implied warranty claim could proceed unless it "rested on allegations about standards other than those permitted by the FDA . . ."[3]; *Gelber v. Stryker Corp.*, No. 09-Civ-1322, 2011 U.S. Dist. LEXIS 41758, at *22 (S.D.N.Y. Apr. 18, 2011) (concluding that "Plaintiffs' implied warranty claims are not preempted to the extent they allege a defective manufacturing claim . . ."); *Purcel*, 2010 U.S. Dist. LEXIS 67109, at *38-39; *Kallal v. Ciba Vision Corp.*, No. 09-CV-3346, 2010 U.S. Dist. LEXIS 56838, at *8 (N.D. Ill. June 9, 2010) (concluding that the plaintiff's claims related to violation of a federal standard could proceed). Most post-*Riegel*

[3] The court in *Hofts* relied in part on 21 C.F.R. § 808.1(d)(1), to conclude that the implied warranty claims were not preempted. 597 F. Supp. 2d at 839. Section 808.1(d)(1) states that "Section 521(a) [of the FDCA, or 21 U.S.C. § 360k] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1). The Supreme Court rejected a similar argument in *Riegel*. 552 U.S. at 328-29. We do not address this issue, as we do not rely on this regulation in holding that Bass's implied warranty claims may proceed.

cases that have found implied warranty claims preempted either concluded that the claims failed to rely on violations of the FDA's requirements, or the plaintiff pleaded that the defendants complied with the FDA's requirements. *E.g.*, *Horn v. Boston Sci. Neuromodulation Corp.*, No. CV409-074, 2011 U.S. Dist. LEXIS 102164, at *16-19 (S.D. Ga. Aug. 26, 2011) (dismissing an implied warranty claim but stating that the claim would have survived if the plaintiff had properly pleaded a failure to comply with FDA requirements); *Walker v. Medtronic, Inc.*, No. 2:07-00317, 2010 U.S. Dist. LEXIS 125103, at *21 (S.D. W. Va. Nov. 24, 2010) (finding that the implied warranty claim was preempted because there was no allegation of non-compliance with FDA standards); *Yost v. Stryker Corp.*, No. 2:09-Cv-28-FtM-29DNF, 2010 U.S. Dist. LEXIS 27079, at *12-13 (M.D. Fla. Mar. 23, 2010) (same). *But see In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1163-64 (D. Minn. 2009) (concluding that the plaintiff's implied warranty claim was preempted despite the plaintiff's allegation that the device was not manufactured in accordance with CGMPs), *aff'd*, 623 F.3d 1200 (8th Cir. 2010).

We agree with the courts that hold that an implied warranty claim is not preempted if the plaintiff alleges that the defendant violated federal requirements *and* can ultimately show a causal link between the violation and the breach of the implied warranty. If, however, the plaintiff claims that the defendant breached the implied warranty despite its compliance with FDA requirements, that claim is clearly preempted, as it would be "'different from, or in addition to,' the requirements imposed by federal law." *See Riegel*, 552 U.S. at 330 (quoting 21 U.S.C. § 360k(a)(1)).

Here, the issue is whether Bass sufficiently pleaded that his breach of implied warranty claims are causally related to Stryker's alleged violations of the FDA's requirements. Bass incorporated all of his factual allegations into his

claim that Stryker breached the implied warranties of merchantability and fitness for a particular purpose, and he sets out that Stryker manufactured the Shell in violation of the FDA requirements and received the Warning Letter from the FDA because the Shell was "adulterated." Therefore, although this portion of the complaint is not a model of clarity, to the extent that he bases his breach of implied warranty claims on violations of federal requirements, those claims survive. To the extent he alleges that Stryker complied with the FDA requirements, his implied warranty claims are preempted.

5. DTPA

Finally, Bass asserts a violation of the DTPA. Stryker's briefing before the district court noted that the Texas Supreme Court found that DTPA claims are preempted by the PMA in *Worthy*. 967 S.W.2d at 376-77. *Worthy* is distinguishable because the plaintiff in that case did not "contend that [the drug] was manufactured, marketed, or injected in her in any way other than that approved by the FDA." *Id.* at 376. Here, of course, Bass does allege that the Shell was manufactured in violation of FDA regulations.

It appears that Bass alleges two theories of violation of the DTPA: misrepresentation and breach of implied warranty. To the extent that Bass's claim relies on a misrepresentation, it is essentially asserting a failure to warn claim that is preempted for the reasons discussed above. To the extent that Bass's DTPA claim relies upon a breach of implied warranty, we allow it to go forward, subject to the limitations discussed in the implied warranty section above.

IV. CONCLUSION

For the foregoing reasons, we AFFIRM the dismissal of Bass's strict liability, negligence, and DTPA claims inasmuch as they are premised on a

failure to warn or a marketing defect; AFFIRM as to Bass's breach of express warranty claims; and REVERSE and REMAND the following: (1) Bass's strict liability claim, to the extent it is based on a manufacturing defect; (2) his negligent manufacturing claim; (3) his claim for breach of an implied warranty; and (4) his DTPA claim, to the extent that it relies on a breach of an implied warranty.