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Don't Overlook Pleading Challenges In State Pharma Suits

Law360, New York (February 9, 2017, 11:44 AM EST) -- The U.S. Supreme Court's decisions in Bell Atlantic Corp. v. Twombly and Ashcroft v. Iqbal released a torrent of challenges to the sufficiency of plaintiffs' pleadings in federal court, including in pharmaceutical product liability cases.[1] However, in state court lawsuits — in which more traditional notice pleading standards typically still govern — defendants have been less likely to challenge poorly-pled complaints.

John DeBoy

Despite this reticence, decisions and experience show that state court challenges to insufficiently-pled complaints can be fruitful for pharmaceutical defendants seeking to narrow the scope of litigation and educate the court on important issues.

Challenges to Pleadings Under a Traditional Notice Pleading Standard

Annie Wang

In Twombly and Iqbal, the Supreme Court announced a shift from a pure notice pleading standard — under which a complaint is sufficiently pled if it simply places the defendant on notice of the plaintiff's claims — to a "plausibility" standard.

Under this standard, a plaintiff's claim should be dismissed if its supporting factual allegations render the claim merely "conceivable" — as opposed to one that states "a claim to relief that is plausible on its face."[2]

Because Twombly and Iqbal have effectively created a more onerous pleading burden, defendants in federal suits have become increasingly likely to challenge plaintiffs' allegations at the pleadings stage — sometimes successfully — including in pharmaceutical product liability cases.[3]

In state courts, however, where more traditional notice pleading standards still typically reign, defendants have been relatively more hesitant to challenge the sufficiency of plaintiffs' factual allegations.

This tendency to eschew insufficient-pleading challenges might be advisable for complaints (or individual claims) containing at least some reasonable degree of factual detail. However, defendants — including in product liability cases — are often too quick to proceed to immediately answering the complaint even when a motion to dismiss might be fruitful.[4]

As several decisions show, state courts in traditional notice pleading jurisdictions are sometimes amenable to requiring plaintiffs to plead with more factual specificity, particularly when a complaint contains little more than conclusory assertions of legal claims.

For instance, in Allstate Ins. Co. v. Electrolux Home Prods. Inc., the Ohio Court of Appeals affirmed the dismissal of a plaintiff's complaint asserting claims for design defect, manufacturing defect, breach of express and implied warranties, failure to warn and negligence against a gas dryer manufacturer.[5]

The court held that the two-page complaint "has set forth only conclusory statements" and that, "[e]ven under Ohio's notice pleading standard, [plaintiff's] complaint is insufficient."[6]

Similarly, in Chalk v. Bertholf, the Mississippi Court of Appeals held that the plaintiffs' complaint was properly dismissed because it failed to plead sufficient facts related to an allegedly slanderous statement made during a radio show.[7] The court noted that, despite "the relaxed, notice-pleading requirements of Mississippi Rule of Civil Procedure 8," the complaint's "[f]ailure to provide any substance regarding the allegedly slanderous words ... was fatal to the appellant[s'] claim."[8]

These and other decisions show that state courts are sometimes amenable to requiring plaintiffs to plead sufficient facts to demonstrate that they have good-faith bases for their claims. Like other defendants, pharmaceutical companies should not hesitate to challenge the sufficiency of poorly-pled complaints under appropriate circumstances, particularly when plaintiffs' allegations amount to little more than conclusory assertions of product liability claims (e.g., "failed to warn," "was defective in design," or "was defective in manufacturing").

Benefits of Pleadings Challenges

Although dismissals with prejudice on insufficient-pleading grounds are rare — and sometimes not permissible in the first instance[9] — filing a motion that holds a plaintiff to task on her pleading obligations can have several advantages for pharmaceutical product liability defendants.

Educating the Court

Pharmaceutical product liability cases routinely present legal and factual issues with which many judges are unfamiliar. These include the learned intermediary doctrine, the federal regulatory framework for prescription medicines and medical devices, federal preemption, and various complex factual issues involving science and medicine.[10]

Judges with limited prior exposure to such issues often do not confront them until late in the case, frequently at the summary judgment stage. However, by filing a well-written motion to dismiss that explains such issues to the court, a defendant can educate the court at the very outset of the litigation.

This, in turn, can help the court understand the weaknesses of a plaintiff's more questionable claims and potentially elicit rulings — including during discovery disputes — that more fairly align with the legitimate scope and viability of the case.

Narrowing the Scope of Litigation

Plaintiffs bringing pharmaceutical product liability cases frequently adhere to a "kitchen sink" approach

in their pleadings, coupling potentially more plausible claims (such as failure to warn) with other claims (such as design defect and manufacturing defect claims) that tend to be more factually unlikely or more vulnerable to legal challenge.

By moving to dismiss at the outset of the litigation, pharmaceutical defendants might succeed in jettisoning the less viable claims and narrowing the scope of the litigation. As reported by Law360, this approach resulted in a Texas state judge's dismissal of non-viable design defect claims against a pharmaceutical manufacturer, as well as an award of attorneys' fees to the defendant, in 2015.[11]

Requiring the Plaintiff to Articulate a Theory

Conclusory or vague claims unsupported by factual allegations can be difficult to defend. In particular, when a defendant allows such a claim to proceed beyond the pleadings stage unchallenged, it can be difficult to appropriately cabin discovery because the basic factual contours of the claim are unknown.

By filing a motion to dismiss on insufficient-pleading grounds, however, a defendant might force a plaintiff to articulate more clearly a factual theory in an amended pleading, thereby making it easier for the defendant to understand the claims and appropriately resist discovery that exceeds the boundaries of the alleged facts.

Several state court decisions articulate the basic due-process principle that a defendant has a right to understand the factual basis for a claim so that it can adequately defend itself.[12]

Demonstrating a Willingness to Fight

Filing a thoughtfully-written motion to dismiss also signals to the plaintiff that the defendant will not acquiesce to common plaintiff tactics and stands ready to vigorously defend the claims against it.

A pleadings challenge can therefore demonstrate to the plaintiff's counsel that litigating the case will require a significant investment of time and resources, which may decrease the net value of the case in the plaintiff's lawyer's estimation and potentially make it easier to settle the case for a reasonable sum.

Other Considerations

Another consideration unique to the pharmaceutical context is the possibility of introducing the medicine's (or device's) FDA-approved warnings at the pleadings stage.

Although a court may not ordinarily consider evidence outside the pleadings when ruling on a motion to dismiss, many states permit a court to consider documents integral to the complaint (including labeling containing the warnings challenged in a failure-to-warn suit),[13] or to take judicial notice of official government acts, including the FDA's approval of drug or device labeling.[14]

Particularly in cases in which the defendant issued strong warnings for its medicine or device, a motion to dismiss that incorporates those warnings can educate the judge on the weaknesses of the plaintiff's claims and, on occasion, result in a favorable adequacy ruling.[15]

A final consideration relates to cost. Because motions to dismiss are ordinarily limited to discussion of the factual allegations in the complaint (and related integral documents), they typically do not require time-consuming review and discussion of evidentiary materials.

This makes them relatively inexpensive to prepare and file (compared to summary judgment motions), and therefore cost-effective in light of their potential benefits. Moreover, much of the legal research performed at the pleadings stage can be leveraged in later stages of the litigation, meaning that costs invested are not fully lost even if a dismissal motion is unsuccessful.

Conclusion

Despite a tendency for state-court pharmaceutical defendants to bypass motions to dismiss and proceed directly to answering the plaintiff's complaint, experience shows that pleadings challenges in state suits can have tangible benefits — even when they do not succeed in terminating the litigation.

Companies defending pharmaceutical product liability suits in state courts should therefore consider challenging claims on pleading-sufficiency grounds, particularly for claims supported principally (or exclusively) by non-factual conclusory assertions.

The benefits that flow from this approach do not adhere solely to defendants operating under the less forgiving Twombly/Iqbal framework in federal court.

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[1] Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007); Ashcroft v. Iqbal, 556 U.S. 662 (2009).

[2] Twombly, 550 U.S. at 570; see also Iqbal, 556 U.S. at 678.

[3] See, e.g., Strayhorn v. Wyeth Pharms. Inc., 737 F.3d 378, 399-400 (6th Cir. 2013) (affirming dismissal of claims against generic pharmaceutical manufacturers under Iqbal); Salvio v. Amgen Inc., 810 F. Supp. 2d 745, 751-58 (W.D. Pa. 2011) (granting motion to dismiss all counts of product liability action because plaintiff "failed to plead facts" sufficiently under Twombly/Iqbal); see also Cecil et al., Motions to Dismiss for Failure to State a Claim After Iqbal, at 8-9, Federal Judicial Center (Mar. 2011) (discussing increase in 12(b)(6) motions following Twombly/Iqbal), available at http://www.fjc.gov/public/pdf.nsf/lookup/motioniqbal.pdf/$file/motioniqbal.pdf.

[4] See, e.g., Howard v. Omni Hotels Mgmt. Corp., 136 Cal. Rptr. 3d 739, 752-53, 763 (Cal. Ct. App. 2012) (affirming summary judgment for bathtub manufacturer in product liability action and suggesting that motion to dismiss might have been successful in light of plaintiff's "somewhat conclusory allegations").

[5] Allstate Ins. Co. v. Electrolux Home Prods. Inc., 2012 WL 112991, at *1-2 (Ohio Ct. App. Jan. 12, 2012).

[6] Id. at *2.

[7] Chalk v. Bertholf, 980 So. 2d 290, 298-99 (Miss. Ct. App. 2007).

[8] Id. at 299; see also Piro v. McKeever, 782 S.E.2d 367, 372 (N.C. Ct. App. 2016) (affirming grant of motion to dismiss in tort action because "Plaintiff [made] conclusory allegations but fail[ed] to assert any facts depicting conduct by defendant"), aff'd by an equally divided court, 794 S.E.2d 501 (N.C. 2016).

[9] See, e.g., Grant v. Grant, 326 So. 2d 758, 760 (Ala. Civ. App. 1976) ("Even when dismissal is granted upon the ground of failure to state a claim, Rule 78 ARCP grants an automatic right to amend within 10 days of the order of dismissal.").

[10] See, e.g., Wyeth Inc. v. Weeks, 159 So. 3d 649, 660, 672-73 (Ala. 2014) (discussing learned intermediary doctrine, federal preemption, failure to warn, and other pharmaceutical product liability issues).

[11] Daniel Langhorne, Genentech Beats Avastin Off-Label Injury Claims in Texas, Law360, Oct. 30, 2015.

[12] See, e.g., WP Devon Assocs. L.P. v. Hartstrings LLC, 2012 WL 3060513, at *4-5 (Del. Super. Ct. July 26, 2012) (granting motion to dismiss because plaintiff failed to plead facts to put defendant "on sufficient notice so that it may defend itself against [] plaintiff's allegations"); Highland Paving Co. LLC v. First Bank, 742 S.E.2d 287, 293 (N.C. Ct. App. 2013) (recognizing that "a complaint must ... state enough to give the substantive elements of a legally recognized claim or it may be dismissed under Rule 12(b)(6)").

[13] See, e.g., Presto v. Sandoz Pharms. Corp., 487 S.E.2d 70, 73 (Ga. Ct. App. 1997) (allowing consideration of warning label and affirming grant of motion to dismiss).

[14] See, e.g., Lutz-Cummings v. Medtronic Inc., 2016 WL 3082314 (Minn. Dist. Ct. May 31, 2016) ("The Court takes judicial notice that Plaintiff's Model 8637 Device and all its components have received federal approval through the FDA's Premarket Approval ('PMA') process, the FDA's most rigorous standard for medical devices."); Meyers v. Bayer AG, Bayer Corp., 735 N.W.2d 448, 469 (Wis. 2007) ("Judicial notice may also be taken of facts from the public records of government agencies, here the PTO and the FDA.").

[15] See, e.g., Banner v. Hoffmann-La Roche Inc., 891 A.2d 1229, 1239 (N.J. App. Div. 2006) (affirming dismissal at pleadings stage because medicine's birth defect warning was adequate as a matter of law).
