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MOTIONS
PRODUCT LIABILITY

New pleading standards, articulated by the U.S. Supreme Court in Twombly and Iqbal, remain an oft-used, potentially potent weapon in the courtroom, say attorneys Anand Agneshwar and Paige Sharpe in this BNA Insight. The authors offer practical advice on when litigators should file a "Twiqbal"motion in product liability cases, including toxic tort suits, as well as best practices for drafting the motion.

Making the Most of *Twombly/Iqbal* in Product Liability Cases


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Five years have elapsed since the U.S. Supreme Court articulated a new iteration of the pleading standard under Federal Rule of Civil Procedure 8(a) in *Bell Atlantic Corp. v. Twombly*, [1] and three years have passed since the Court clarified the scope and application of *Twombly* in *Ashcroft v. Iqbal*. [2] Those cases generated immediate buzz among academics, practitioners, and legislators. While the torrent of commentary appears to be slowing in the academic and legislative spheres, [3] *Twombly* and *Iqbal* remain an oft-used, potentially potent weapon in the courtroom. In the products realm in particular, defense attorneys repeatedly have employed *Twiqbal* motions to win dismissals of complaints or to force plaintiffs to say in their complaints—and not after discovery—precisely what they seek to prove. This article discusses the analysis in which counsel should engage in deciding whether to file a *Twiqbal* motion as well as best practices for drafting the motion.

[1] 550 U.S. 544 (2007).

[2] 556 U.S. 662 (2009).

[3] For example, a recent Westlaw search shows that in 2010, the year after *Iqbal* was handed down, law reviews and journals published some 91 articles with "Iqbal" in the title. That number dropped to 35 or so in 2011, and just eight such articles have been published in the first four months of 2012. On the legislative front, Senator Arlen Specter's effort to overturn *Iqbal* through congressional action died after introduction, as did a similar proposal by Rep. Jerrold Nadler. *See* Notice Pleading Restoration Act of 2009, S. 1504, 111th Cong. (2009), *available at* http://www.govtrack.us/congress/bills/111/s1504; Open Access to Courts Act of

2009, H.R. 4115, 111th Cong. (2009), *available at* http://www.govtrack.us/congress/bills/111/hr4115.

The *Twiqbal* Two-Step

First, a refresher. Under Rule 8(a), a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." [4] For more than 50 years before *Twombly*, the oft-quoted language of *Conley v. Gibson* provided the standard for evaluating a motion to dismiss: "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." [5] *Twombly* retired the "no set of facts" language of *Conley*, and in its place issued a plausibility standard under which plaintiffs must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." [6] In order to "nudge[] their claims across the line from conceivable to plausible," plaintiffs must provide a complaint with "enough heft to show that the pleader is entitled to relief." [7] As justification for its holding, the Court cited the need "to avoid the potentially enormous expense of discovery in cases with no reasonably founded hope that the discovery process will reveal relevant evidence." [8]

[4] Fed. R. Civ. P. 8(a).

[5] *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957).

[6] *Twombly*, 550 U.S. at 555.

[7] *Id.* at 557, 570 (internal quotation and alteration omitted).

[8] *Id.* at 559 (internal quotation and alteration omitted).

Twombly involved antitrust claims, raising questions about whether its pleading directives applied in all civil cases in federal court. [9] The Court answered in the affirmative in *Iqbal*, [10] and further reiterated that "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." [11] As a result, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." [12] Based on these principles, *Iqbal* set forth a two-step process for assessing the sufficiency of a complaint. The analysis begins "by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." [13] After weeding out conclusory assertions, a court should consider whether the remaining "well-pleaded factual allegations . . . plausibly give rise to an entitlement to relief." [14]

[9] The circuit courts split in their response. The Sixth Circuit, for example, applied *Twombly* to all civil claims. *See Total Benefits Planning Agency, Inc. v. Anthem Blue Cross and Blue Shield*, 552 F.3d 430, 434 n.2 (6th Cir. 2008) ("This Court has cited the heightened pleading standard of *Twombly* in a wide variety of cases, not simply limiting its applicability to antitrust actions."). The majority of circuits, however, adopted a "flexible" standard or "sliding scale," whereby more facts were needed to support complex causes of action such as RICO and antitrust claims. *See, e.g., Iqbal v. Hasty*, 490 F.3d 143, 157-58 (2d Cir. 2007), *overruled by Iqbal*, 556 U.S. 662.

[10] *See Iqbal*, 556 U.S. at 684 ("Our decision in *Twombly* expounded the pleading standard for 'all civil actions.'" (citing Fed. R. Civ. P. 1)).

[11] *Id.* at 678.

[12] *Id.* (citing *Twombly*, 550 U.S. at 555).

[13] *Id.* at 679.

[14] *Id.*

Twiqbal Motions in Products Cases

The sheer number of cases applying *Twombly* and *Iqbal* makes it a challenge to keep abreast of developments in the case law, [15] even in a discrete practice area such as product liability litigation. Empirical analyses chiefly have looked at the impact of *Twombly* and *Iqbal* across federal civil litigation as a whole, [16] and their conflicting methodologies and interpretive frameworks have generated mixed reviews of trends in the case law. [17] A 2011 law review article, for example, which focused on pharmaceutical and medical device litigation, concluded that "*Iqbal* is not having a dramatic impact on

this cohort, although its impact cannot be conclusively dismissed as inconsequential either." [18] The author found that the deciding court relied on *Iqbal* in granting a dismissal in about 21 percent of the 264 cases studied, [19] but noted a pattern of reducing incidence, no obviously explainable geographic concentrations, and a frequent grant of amendment opportunities. [20]

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[15] As of May 1, 2012, Westlaw reported 60,817 cases citing *Twombly* and 38,804 cases citing *Iqbal*.

[16] *See, e.g.*, Joe S. Cecil et al., Fed. Judicial Ctr., Motions to Dismiss for Failure to State a Claim After *Iqbal*: Report to the Judicial Conference Advisory Committee on Civil Rules (2011); Patricia Hatamyar Moore, *An Updated Quantitative Study of* Iqbal*'s Impact on 12(b)(6) Motions*, 46 U. Rich. L. Rev. 603 (2012); Patricia W. Hatamyar, *The Tao of Pleading: Do* Twombly *and* Iqbal *Matter Empirically?*, 59 Am. U. L. Rev. 553 (2010); *Kendall W. Hannon,* Note, *Much Ado About* Twombly*? A Study on the Impact of* Bell Atlantic Corp. v. Twombly *on 12(b)(6) Motions*, 83 Notre Dame L. Rev. 1811 (2008).

[17] For example, Professor Hatamyar Moore finds a statistically significant increase in the chances of a 12(b)(6) motion being granted under *Iqbal* versus *Conley*, while a report to the Judicial Conference Advisory Committee on Civil Rules finds such an increase only in cases involving financial instruments. *Compare* Hatamayer Moore, *supra* note 16, at 604, *with* Cecil, *supra* note 16, at 5.

[18] William M. Janssen, Iqbal *"Plausibility" in Pharmaceutical and Medical Device Litigation*, 71 La. L. Rev. 541, 645 (2011).

[19] *Id.*

[20] *Id.* at 643.

Such empirical analyses cannot account for more subtle impacts that *Twombly* and *Iqbal* may be having in the products field. For example, plaintiff's counsel presumably are aware of the new pleading standard and may be drafting complaints designed to withstand *Twiqbal* motions. Whether or not the success rate has changed, defense counsel may be filing more motions to dismiss than in the past and challenging complaints that would easily have met the prior "no set of facts" standard, resulting in more net wins as a whole. It is, moreover, not uncommon for a defendant to agree to withdraw such a motion and give the plaintiff an opportunity to amend; such circumstances may not be captured by studies that examine the outcome of motions to dismiss.

There are suggestions, however, that products litigators are successfully capitalizing on the *Twiqbal* standard. The Drug & Device Law blog reviewed 354 *Twiqbal* motions in August 2009 and concluded both that "there's precedent out there for dismissing virtually any product liability-related claim under *Iqbal/Twombly*—provided the complaint is vague enough," and that "the pace and scope of *Iqbal/Twombly* dismissals in product liability cases is increasing." [21] The blog keeps a "*Twiqbal* cheat sheet" with a running tab of outcomes covering a range of claims, from negligence to warranty to strict products liability, and listed more than 90 wins as of the end of April 2012. [22]

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[21] James M. Beck & Mark Herrmann, *Twombly/Iqbal* And Product Liability: How Much Progress Is There?, Drug & Device L. Blog (Aug. 9, 2009, 4:50 PM), http://druganddevicelaw.blogspot.com/2009/08/twomblyiqbal-and-product-liability-how.html.

[22] James M. Beck, *Twiqbal* Cheat Sheet, Drug & Device L. Blog (May 13, 2010, 3:27 PM), http://druganddevicelaw.blogspot.com/2010/05/twiqbal-cheat-sheet.html.

To File or Not to File

Evaluate the Judge

Although it may be difficult to spot clear trends in the litigation, any given federal judge—unless new to the bench—almost certainly has applied *Twiqbal* more than a handful of times. The first step in evaluating a complaint is thus assessing your assigned judge's inclinations. Whether your judge has ruled on a *Twiqbal* motion in another products case in particular is, of course, valuable information in deciding whether to file such a motion.

Beyond simply running a search for citations to *Twombly* and *Iqbal* by your judge, you may have other resources at your disposal to determine whether the judge would likely grant your motion. To the extent one of your goals may be to educate the judge about the underlying facts, *see* discussion *infra*, it would be useful to know whether the judge is likely to embrace the opportunity to learn about the

case or to disregard background information. Even if your judge has not ruled on a *Twiqbal* motion in the products arena, other district judges in the jurisdiction—or even the appellate court—may have issued such rulings. [23]

[23] The Fifth, Sixth, and Eleventh Circuits have upheld dismissals of products claims in drug or medical device cases. *See Funk v. Stryker Corp.*, 631 F.3d 777, 782 (5th Cir. 2011) (affirming dismissal of a manufacturing defect claim when the complaint failed to plead how the manufacturing process failed, how it deviated from FDA specifications, and the causal connection between the violation and the plaintiff); *Patterson v. Novartis Pharms. Corp.*, 451 Fed. Appx. 495, 497-98 (6th Cir. 2011) (affirming dismissal of products claims because the plaintiff did not sufficiently identify the drug taken); *Bailey v. Janssen Pharmaceutica, Inc.*, 288 Fed. Appx. 597, 609 (11th Cir. 2008) (affirming dismissal of a failure to warn claim because the complaint nowhere recited the contents of the warning label or the information available to the plaintiff's physician). *But see id.* (finding that the plaintiff had adequately alleged a design or manufacturing defect claim and reversed the district court on that point). An appeal in a pharmaceutical products case, dismissed with prejudice by the D.C. district court, has been fully briefed and is pending before the D.C. Circuit Court of Appeals. *See Rollins v. Wackenhut Servs.*, 802 F. Supp. 2d 111 (D.D.C. 2011), *appeal docketed*, No. 11-7094 (D.C. Cir. Sept. 9, 2011).

Evaluate the Complaint

In order to assess the strength of a potential *Twiqbal* motion—and as a pre-drafting exercise—you should assess the strength of the individual claims of the complaint. Pre-*Iqbal* case law typically provides that a complaint must adequately allege the individual elements of the claim on which the plaintiff's theory of liability is based. [24] After *Iqbal*, a court must conduct a close comparison between the essential elements of proof and the factual allegations in a complaint to determine whether the plaintiff has adequately stated a claim. Dismissals of products cases under the *Twiqbal* regime typically are based on the plaintiff's failure to allege facts to support an essential element of a claim, such as how a product is defectively designed (design defect claim) or what about the product labeling is insufficient (failure to warn claim). [25] A complaint that is missing essential elements of a claim—or that contains only conclusory allegations regarding those elements—is vulnerable to attack.

[24] *See, e.g., Gagliardi v. Sullivan*, 513 F.3d 301, 305 (1st Cir. 2008) (a complaint must "set forth factual allegations, either direct or inferential, respecting each material element necessary to sustain recovery") (internal quotation omitted); *Johnson v. Riverside Healthcare Sys.*, 534 F.3d 1116, 1122 (9th Cir. 2008) ("At the motion to dismiss stage . . . [a] complaint must allege sufficient facts to state the elements of [the relevant] claim."); *Rios v. City of Del Rio*, 444 F.3d 417, 420-21 (5th Cir. 2006) (a complaint must contain sufficient allegations on "every material point necessary to sustain a recovery"); *Stern v. Gen. Elec. Co.*, 924 F.2d 472, 476 (2d Cir. 1991) ("[A] motion to dismiss must be granted if the pleadings fail adequately to allege the elements of the claim on which the plaintiff's theory of liability is is based.").

[25] *See, e.g., Rollins v. Wackenhut Services*, 802 F. Supp. 2d 111 (D.D.C. 2011) (finding that the plaintiff failed to state a claim for manufacturing defect, design defect, or failure to warn under Restatement (Second) of Torts § 402A); *Frey v. Novartis Pharms. Corp.*, 642 F. Supp. 2d 787, 795 (S.D. Ohio 2009) (dismissing a design defect claim because plaintiffs "simply provided a formulaic recitation of the elements of a claim under the statute"); *Mills v. Bristol-Myers Squibb Co. (Mills I)*, No. CV 11-968-PHX-FJM, 2011 BL 209710, at *3-4 (D. Ariz. Aug. 12, 2011) (dismissing claims ranging from strict products liability and misrepresentation to breach of express and implied warranties because the complaint was "completely devoid of any facts linking the behavior of defendants to plaintiff"); *Lewis v. Abbott Labs*, No. 08 Civ. 7480, slip op. at 1-3 (S.D.N.Y. July 24, 2009) (dismissing products liability claims due to the plaintiff's failure to allege facts to support essential elements).

This assessment requires casting a critical eye on the complaint. Disregard its length: A 100-paragraph pleading replete with boilerplate language is as subject to a *Twiqbal* motion as a skimpy 10-paragraph complaint. [26] Resist relying on your familiarity with the facts behind an allegation. For example, a generic citation to promotional materials in a failure to warn case should be insufficient if the plaintiff never identifies specific advertisements and how they are relevant to his or her claims, e.g., because he or she viewed them and relied on them in using the product. A blanket statement that the risk of the product outweighs its benefits is a conclusory allegation that does not advance a design defect claim.

[26] The complaint in *Mills v. Bristol-Myers Squibb Co.*, for example, comprised 123 paragraphs and 29 pages. Plaintiff's First Am. Compl., *Mills v. Bristol-Myers Squibb Co.*, No. 2:11-cv-00968 (D. Ariz. Jan. 1, 2011). The court nonetheless dismissed because the plaintiff's allegations were conclusory and lacked factual content. *Mills I*, 2011 BL 209710, at *3. After the plaintiff filed a proposed amended complaint that failed to correct the deficiencies, the court dismissed the case with prejudice. *Mills v. Bristol Myers Squibb Co. (Mills II)*, No. CV 11-00968-PHX-FJM, 2011 BL 260049, at *4 (D. Ariz. Oct. 7, 2011).

On the other hand, if the motion does not seem strong in light of a well-crafted complaint, opening the case with a losing pleading motion is not helpful, so choose your battles carefully.

Evaluate Your Goals

A *Twiqbal* motion can have ancillary benefits beyond the grant or denial of the motion, and these should go into the analysis of whether to file. First, a plaintiff may offer to amend if the motion is withdrawn or the court may grant leave to amend rather than dismiss with prejudice. In either circumstance, the net result is a complaint with facts on the table. Second, a motion might limit a case by resulting in partial dismissal; for example, design defect claims may be dismissed because the plaintiff has not cited a feasible alternative design, but failure to warn claims may proceed because the plaintiff has specifically alleged a purported deficiency in the product labeling. Third, the motion can allow you to preview coming arguments and develop themes, thereby educating the judge on the substance of the case and creating opportunities to emphasize your position. Note that this opportunity also puts a premium on early preparation; counsel must get up to speed quickly on the underlying facts, the applicable law, and the defense theory of the case.

A *Twiqbal* motion conversely can have unintended negative effects, which you should also consider. Just as the motion can educate the judge, it can tip your hand to the plaintiff, giving him or her an early opportunity to begin developing an opposing strategy to your specific arguments. The motion also may provide the plaintiff with a roadmap for how to amend the complaint in a way that makes it more substantive and focused, resulting in a pleading that is more difficult to defeat. Moreover, an adverse decision risks unfavorable law of the case that could weaken a later summary judgment motion. Finally, you should limit the motion to matters contained in the complaint, with perhaps some citation to matters of public record, [27] or you risk having it converted prematurely into a motion for summary judgment.

[27] Federal courts may consider publicly available information in ruling on a motion to dismiss. *See, e.g., Lee v. City of Los Angeles*, 250 F.3d 668, 689 (9th Cir. 2001) ("A court may take judicial notice of matters of public record without converting a motion to dismiss into a motion for summary judgment.") (internal quotation omitted); *United States v. Wood*, 925 F.2d 1580, 1582 (7th Cir. 1991) ("A district court may take into consideration documents incorporated by reference to the pleadings" and "may also take judicial notice of matters of public record."); *Horne v. Novartis Pharm. Corp.*, 541 F. Supp. 2d 768, 776-77 (W.D.N.C. 2008) (pharmaceutical package insert considered on a motion to dismiss a failure to warn claim).

The Motion

Once you have decided to draft the motion, but before putting pen to paper, check and double-check the local rules and the judge's standing orders. Such guides not only provide technical requirements such as page limits and margin settings, but also may impose rules on how motions to dismiss are filed. [28] Judges may require that the moving party first meet and confer with opposing counsel, or may obligate the moving party to seek permission of the court to file the motion. Local rules and standing orders thus may inform decisions about when to file and whether, for example, to allow the plaintiff a shot at amendment in advance of the motion.

[28] *See, e.g.*, Individual Practices of United States District Judge Victor Marrero, Southern District of New York (Sept. 1, 2010), *available at* http://www.nysd.uscourts.gov/judge/Marrero (requiring a pre-motion conference and a letter from the defendant to the plaintiff setting forth the pleading deficiencies and providing that the plaintiff may seek leave to amend).

The background section of the motion provides an ideal opportunity to educate the judge about the product involved and associated qualities, such as the breadth of its use and the adequacy of its warnings. You may consider attaching the product label to the motion or citing, in a prescription drug

case, to the drug approval history by FDA. [29] If other courts have considered and dismissed similar claims, especially claims involving your product, those cases deserve a citation here.

[29] FDA has a dedicated website that provides drug labels and approval histories. *See* http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.

In regard to the legal standard and argument, *Iqbal* itself provides the two-step roadmap for a *Twiqbal* motion. Explain which allegations the judge should disregard as conclusory, and how the remaining factual allegation fails to address essential elements of the plaintiff's claim.

You may want to preview the plaintiff's likely arguments in order to draw the sting, or you may prefer to see whether the plaintiff in fact raises such points and then address them, if need be, in the reply. Consider whether to seek dismissal with prejudice in your opening brief or, upon the plaintiff's failure to address the complaint's defects in the opposition, make the case for dismissal with prejudice in the reply.

Finally, you should strategically order multiple arguments, especially to the extent that you are seeking dismissal of multiple claims. Does it make sense to attack the claims in the order in which they are presented in the complaint, or do you lead with your strongest position? Do you leave your weakest argument for last, or do you bury it in the middle? Can you group claims because they all are subject to the same attack? For example, in a state that abrogates common law products liability claims, [30] you may want to address any and all non-statutory claims by simply stating that they are not viable. Also consider whether and when to raise arguments in the alternative, e.g., your motion may address both the plaintiff's standing to bring a claim and his or her failure to plead the claim adequately. You will need to decide which to argue first and whether your points may dovetail.

[30] For example, the Louisiana Products Liability Act (the "LPLA") "expressly provides 'the exclusive theories of liability for manufacturers for damage caused by their products.' . . . Thus, Louisiana law eschews all theories of recovery in this case except those explicitly set forth in the LPLA." *Jefferson v. Lead Indus. Ass'n, Inc.*, 106 F.3d 1245, 1248 (5th Cir. 1997) (quoting La. R.S. 9:2800.52).

The Reply

A few words regarding the reply. Given the rapid pace of *Twiqbal* decisions, case law developments may well have occurred since the time that you filed your opening brief. It is especially important in the *Twiqbal* context, therefore, that you recheck the cases you cited in the opening and run a search for any new opinions.

Your strategic considerations should focus on which opposition points to rebut and which of your arguments the opposition concedes or does not address. If the opposition fails to explain how the plaintiff would cure any defects, consider arguing futility as the basis for dismissal with prejudice. [31] If the opposition requests leave to amend, check the local rules to see whether the plaintiff complied with any applicable requirements and whether case law allows dismissal with prejudice for non-compliance. [32]

[31] *See, e.g.*, *Rollins*, 802 F. Supp. 2d at 125 n.10 (denying leave to amend as futile when the plaintiff failed to file a motion for leave to amend and thereby failed to indicate that she would be able to plead sufficient facts to state a claim for relief).

[32] *See, e.g.*, *Baker v. Library of Congress*, 260 F. Supp. 2d 59, 68 (D.D.C. 2003) (denying leave to amend when the motion was unaccompanied by a proposed amended complaint as required under Local Civil Rule 15.1).

If the opposition suggests that the plaintiff needs discovery in order to allege claims adequately, return to *Twombly* and *Iqbal*: They require adequate pleading *before* exposing a defendant to the burden and expense of discovery. [33]

[33] *See Twombly*, 550 U.S. at 557-60 (discussing at length the importance of weeding out deficient complaints prior to discovery); *Iqbal*, 556 U.S. at 678-79 (Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.").

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