Product Liability - USA

Twombly/*Iqbal* prove potent in products cases

Contributed by **Arnold & Porter LLP**

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Introduction

As the US Supreme Court's most recent articulation of the federal pleading standard, *Bell Atlantic Corp v Twombly*(1) and *Ashcroft v Iqbal*(2) have received their due attention in case law. Since the Supreme Court made clear that the revised standard applies in all civil cases in federal court,(3) any district judge ruling on a motion to dismiss presumably has applied the two cases as binding precedent.(4) While opinions differ on trends in the case law,(5) a group of recent appellate decisions suggest that in the product liability arena, *Twombly* and *Iqbal* are proving effective tools for defence counsel seeking to dismiss cases or narrow claims before engaging in lengthy and costly discovery.

***Twombly*/*Iqbal* framework**

Under Rule 8(a) of the Federal Rules of Civil Procedure, a complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief".(6) 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".(7) *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".(8) Merely pleading facts consistent with wrongdoing is insufficient.(9) 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".(10) 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".(11)

In addition to confirming the broad application of *Twombly*,the court in *Iqbal* 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".(12) As a result, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice".(13) 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".(14) After weeding out conclusory assertions, a court should consider whether the remaining "well-pleaded factual allegations . . . plausibly give rise to an entitlement to relief".(15)

***Twombly* and *Iqbal* in product liability cases**

While district courts have had ample opportunity to apply *Twombly* and *Iqbal* in a range of cases, appellate opinions are fewer and farther between. If a district court grants dismissal with prejudice or denies leave to amend, a plaintiff may file an immediate appeal. However, if the court denies the motion a defendant may need to take affirmative steps to preserve the right to appeal(16) and then proceed to the conclusion of the case before challenging the denial at the appellate level. In most cases, therefore, the appellate court is ruling on a motion to dismiss that was granted below. This holds true in recent rulings in product liability cases applying *Twombly* and *Iqbal*, in which appellate courts have repeatedly have affirmed lower court dismissals of complaints.

Authors

Anand Agneshwar

Paige Hester Sharpe

Dismissal of vague and conclusory claims

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.(17) 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 product cases under the *Twiqbal* regime are typically 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 labelling is insufficient (failure to warn claim).(18)

The Fifth and Ninth Circuits have both applied the *Twombly/Iqbal* analysis in affirming dismissals of manufacturing defect claims. In *Funk v Stryker Corp*,(19) the Fifth Circuit found a complaint regarding a Trident System artificial hip replacement to be "impermissibly conclusory and vague", in that it specified neither the manufacturing defect nor a causal connection between any defect and the alleged injury.(20) The complaint's reliance on the doctrine of *res ipsa loquitur* (the thing speaks for itself) violated the *Iqbal* requirement that a plaintiff state a claim that is plausible on its face.(21) Similarly, the Ninth Circuit in *Nelson v Original Smith & Wesson Business Entities and/or Corporations*(22) applied *Iqbal* to a complaint involving the firing of a revolver that injured a child. While the law allowed recovery when a gun discharges after malfunctioning, the allegation that the gun at issue "may have" discharged in an improper mannerwas a "vague and speculative" assertion that did not pass the *Iqbal* test for specific allegations of fact.(23)

In *Bailey v Janssen Pharmaceutica Inc*,(24) the Eleventh Circuit affirmed in part the dismissal of claims involving a prescription pain-relief patch that allegedly malfunctioned in its dose delivery.(25) The plaintiff alleged failure to warn, a claim subject to the learned intermediary doctrine, by which the duty to warn flows from the drug manufacturer to the physician, not to the ultimate consumer. Applying *Twombly/Iqbal*, the court noted that "[n]owhere does the complaint recite the contents of the warning label or the information available to [the decedent's] physician or otherwise describe the manner in which the warning was inadequate".(26) The complaint's single assertion that the drug's warnings were inadequate "to fully apprise the prescribing physicians of the full nature or extent of the risks" was too conclusory to support a failure to warn claim.(27)

Dismissal for failure to allege injury

Courts have repeatedly held that "purchasers of an allegedly defective product have no legally recognisable claim where the alleged defect has not manifested itself in the product they own".(28) In other words, "[w]hat courts require . . . is that injury be personal".(29) While injury in fact is thus a required element of a product liability claim,(30) the application of *Twombly* and *Iqbal* in a no-injury case differs slightly from their application to a vague or conclusory claim. In the latter, the plaintiff has failed to state the claim with the requisite factual support; in the former, the facts themselves plead the plaintiff out of the claim.

A recent decision of the Eight Circuit illustrates the point. In *O'Neil v Simplicity Inc*,(31) the buyers of a recalled children's crib sued the manufacturer on warranty grounds on behalf of a purported class that excluded individuals who suffered personal injury. The court upheld dismissal on the grounds that the failure of the alleged defect to manifest itself in the plaintiffs' crib was fatal to their case: "[w]here, as in this case, a product performs satisfactorily and never exhibits an alleged defect, no cause of action lies."(32) The court thus premised dismissal on its rejection of a no-injury cause of action,(33) as opposed to the plaintiffs' failure to state sufficient facts to support a cognisable claim.

Dismissal on product identification grounds

An essential element of both negligence and strict products claims is causation - that is, the plaintiff must allege, and eventually prove, that the product at issue caused the claimed injury. Under the law of most jurisdictions, to establish this element of a claim, a product liability plaintiff must prove that the defendant manufactured, distributed or sold the specific product causing the injury.(34) This requirement dovetails with one of the propositions of *Twombly/Iqbal*: that "[w]here a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief".(35) When a plaintiff cannot allege that he or she used or consumed the particular product manufactured by the defendant, the plaintiff has alleged only the possibility of liability; he or she has not nudged the claim from conceivable to plausible.

The Sixth Circuit applied this reasoning in upholding the dismissal of a complaint and denial of leave to amend in *Patterson v Novartis Pharmaceuticals Corp*.(36) The plaintiff claimed to have developed osteonecrosis of the jaw as a result of infusions of the prescription drug Aredia "and/or generic Aredia". After citing the requirement under the applicable state law that "a plaintiff suing a manufacturer in a product liability action be able to prove that his or her injury can be traced to that specific manufacturer", the Sixth Circuit grounded its finding of proper dismissal on an application of *Twombly* and *Iqbal:*

> *"The assertion that Patterson received 'Aredia and/or generic Aredia (pamidronate)' means that Patterson could have received only Aredia manufactured by Novartis. Or, she could have received both Aredia and generic Aredia, which would be sufficient to state a claim against Novartis. However, as pled, it is also entirely plausible that Patterson received infusions of only generic Aredia that Novartis did not manufacture: it is this possibility that is fatal to her complaint. Because the complaint only permits us to infer the possibility that Patterson received infusions of Aredia manufactured by Novartis, it fails to satisfy the pleading standards set forth in Twombly and Iqbal."*(37)

Further applying *Twombly/Iqbal*, the Sixth Circuit held that the lower court properly denied the plaintiff's request for leave to conduct discovery in order to cure the defects of the complaint.(38) Also proper was the denial of a request for leave to amend when the plaintiff did not state with particularity the grounds for amendment, but instead "only mentioned the possibility of amendment in the very last sentence of her opposition brief".(39)

Comment

As the number of cases applying *Twombly/Iqbal* mounts, and as dismissals in product liability cases make their way to the appellate level, a review of initial opinions suggests that the circuit courts are inclined to concur with the lower courts on the insufficiencies of conclusory or non-cognisable claims. With this growing body of precedent to support dismissals, the defence bar has a potentially potent ally in the *Twombly/Iqbal* pleading standard.

For further information on this topic please contact Anand Agneshwar at Arnold Porter LLP's New York office by telephone (+1 212 715 1000), fax (+1 212 715 1399) or email (anand.agneshwar@aporter.com). Alternatively, contact Paige Sharpe at Arnold Porter LLP's Washington DC office by telephone(+1 202 942 5000), fax (+1 202 942 5999) or email (paige.sharpe@aporter.com).

Endnotes

(1) 550 US 544 (2007).

(2) 556 US 662 (2009).

(3) See As the number of cases applying *Twombly/Iqbal* mounts, and as dismissals in product liability cases make their way to the appellate level, a review of initial opinions suggests that the circuit courts are inclined to concur with the lower courts on the insufficiencies of conclusory or non-cognisable claims - *Iqbal*, 556 US at 684 ("Our decision in *Twombly* expounded the pleading standard for 'all civil actions'" (citing Fed R Civ P 1)). Before *Iqbal*, a question remained as to whether *Twombly* applied outside of the antitrust context that the case involved, and the circuit courts were 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 F3d 430, 434 n2 (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"). However, the majority of circuits adopted a 'flexible' standard or 'sliding scale', whereby more facts were needed to support complex causes of action such as Racketeer Influenced and Corrupt Organisations Act and antitrust claims. See, for example, *Iqbal v Hasty*, 490 F3d 143, 157-58 (2d Cir 2007), overruled by *Iqbal*, 556 US 662.

(4) The case law bears out this presumption. As of June 27 2012, Westlaw reported 63,035 federal court opinions citing *Twombly* and 41,315 federal court opinions citing *Iqbal*.

(5) Conflicting methodologies and interpretive frameworks of empirical analyses have generated mixed reviews of trends in the case law. For example, one study finds a statistically significant increase in the chances of a 12(b)(6) motion being granted under *Iqbal* versus *Conley v Gibson*, while a report to the Judicial Conference Advisory Committee on Civil Rules finds such an increase only in cases involving financial instruments. Compare Patricia Hatamyar Moore, "An Updated Quantitative Study of *Iqbal's* Impact on 12(b)(6) Motions", 46 U Rich L Rev 603, 604 (2012), with 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 5 (2011).

(6) Fed R Civ P 8(a).

(7) *Conley v Gibson*, 355 US 41, 45-46 (1957).

(8) *Twombly*, 550 US at 555.

(9) *Id* at 557.

(10) *Id* at 557, 570 (internal quotation and alteration omitted).

(11) *Id* at 559 (internal quotation and alteration omitted).

(12) *Iqbal*, 556 US at 678.

(13) *Id* (citing *Twombly*, 550 US at 555).

(14) *Id* at 679.

(15) *Id.*

(16) For example, an appellate court may require that a party have filed objections to a magistrate judge's recommendation on motion to dismiss at the district court level. See, for example, *Donaldson v Ducote*, 373 F3d 622, 624 (5th Cir 2004).

(17) See, for example, *Gagliardi v Sullivan*, 513 F3d 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 F3d 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 F3d 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").

(18) See, for example, *Rollins v Wackenhut Servs*, 802 F Supp 2d 111 (DDC 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). An appeal in *Rollins*, dismissed with prejudice by the DC district court, has been fully briefed and is pending before the DC Circuit Court of Appeals.

(19) 631 F3d 777 (5th Cir 2011).

(20) *Id.*

(21) *Id.* The Seventh Circuit reached a different result in another case involving the Trident device. In *Bausch v Stryker Corp*, 630 F 3d 546 (7th Cir 2010), the court overturned a dismissal of strict product liability and negligence claims. The complaint alleged that the defendants had received complaints about the Trident and cited a Food and Drug Administration warning letter regarding the very device that allegedly was implanted in the defendant. *Id* at 559. The court found such allegations sufficient to provide the required fair notice of the nature of the claim under *Twombly* and *Iqbal*. *Id.* While the complaint in *Bausch* may provide a guide to the type of pleading likely to withstand a motion to dismiss, the Seventh Circuit also found that "the victim of a genuinely defective product" may be entitled to discovery in order to identify the product defect. *Id* at 560. Such a holding runs counter to the *Twombly/Iqbal* directive and to the conclusions of other circuit courts. *See Twombly*, 550 US at 557-60 (discussing at length the importance of weeding out deficient complaints prior to discovery); *Iqbal*, 556 US at 678-79 (Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions"); see also,for example., *Patterson v Novartis Pharms Corp*, 451 Fed Appx 495, 498 (6th Cir 2011).

(22) 449 Fed Appx. 581 (9th Cir 2011).

(23) *Id.*

(24) 288 Fed Appx 597 (11th Cir 2008).

(25) The court found that the complaint's allegations of specific defects and the decedent's death within a day of using the patch were sufficient to support a defect claim and the requirement of causation. *Id* at 607-08. As with the *Bausch* case cited above, the complaint in *Bailey* may provide a roadmap of the types of allegation necessary to state a claim for defective design or manufacturing defect. Thus, to the extent that a complaint lacks the type of allegations in the *Bailey* pleading, defence counsel may find the *Bailey* opinion useful in arguing for dismissal of a pleading that is deficient in contrast.

(26) *Id* at 609.

(27) *Id* at 608 (alteration omitted).

(28) *Briehl v Gen Motors Corp*, 172 F3d 623, 628 (8th Cir.1999) (citing *Weaver v Chrysler Corp*, 172 FRD 96, 99 (SDNY 1997)).

(29) *Bertulli v Indep Ass'n of Cont'l Pilots*, 242 F3d 290, 294 (5th Cir 2001).

(30) *See Rivera v Wyeth-Ayerst Labs*, 283 F3d 315, 320 (5th Cir 2002).

(31) 574 F3d 501 (8th Cir 2009).

(32) *Id* at 504 (internal quotations omitted).

(33) *Id* at 505.

(34) See, for example, *Waters v NMD-Wollard Inc*, Civil Action 06-0032, 2007 WL 2668008, at *4 (ED Pa Sept 5 2007) ("For claims of negligence and products liability in Pennsylvania, plaintiff must establish that the injuries sustained were caused by the product of a particular manufacturer or supplier") (internal quotation omitted) (citing Pennsylvania cases).

(35) *Iqbal*, 556 US at 678 (citing *Twombly*, 550 US at 557) (internal quotations omitted).

(36) 451 Fed Appx 495 (6th Cir 2011).

(37) *Id* at 497 (internal quotations and citations omitted).

(38) *Id* at 498.

(39) *Id* at 499.