

DRUG & DEVICE
BULLETIN



AUGUST 11, 2009

Pharmaceutical & Medical Device

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**PROPOSED LEGISLATION WOULD REAFFIRM
LENIENCY OF NOTICE-PLEADING STANDARD**

**Supreme Court Opinion That Tightens Pleading Requirements Gaining Traction
in Federal District Courts**

Plaintiffs' and defense counsel alike have been bracing to see whether the U.S. Supreme Court's recent decision in *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), would make it easier for defendants to win dismissals of complaints that plead only minimal facts. Early evidence suggests that federal courts have indeed been more willing to bounce threadbare complaints, prompting proposed legislation that would walk back the Court's decision.

In *Iqbal*—a post-September 11th prisoner detention case seemingly unrelated to drug and device litigation—the Court held that a Pakistani man's complaint did not sufficiently plead facts to support his claim of discrimination by high-ranking federal officials.

So holding, the Court created a roadmap for courts to follow in considering a motion to dismiss. "[A] court . . . can choose to begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth. While legal conclusions can provide the framework of a complaint, they must be supported by factual allegations. When there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief."

Many commentators believe that the U.S. Supreme Court rewrote the law with respect to Rule 8's pleading requirements, making it more difficult for plaintiffs to survive motions to dismiss in federal court.

The central issue is whether the Supreme Court actually heightened Rule 8's pleading requirements by holding that the plaintiff failed to plead sufficient facts to move his discrimination claim "across the line from conceivable to plausible," or whether the Court simply reinforced the existing pleading requirements in the context of a limited cause of action that requires a plaintiff to show that "each Government-official defendant, through the official's own individual actions, has violated the Constitution."

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Whatever the Court's intent, the dissent was clear in its belief that *Iqbal* departed from precedent stating, "The sole exception to [the rule that courts must accept allegations as true] lies with allegations that are sufficiently fantastic to defy reality as we know it: claims about little green men, or the plaintiff's recent trip to Pluto, or experiences in time travel. That is not what we have here."

The New York Times reports that federal courts have already cited *Iqbal* more than 500 times, and many of these courts have used *Iqbal* as a basis to dismiss a plaintiff's complaint.

The U.S. District Court for the Middle District of Florida relied on *Iqbal*, in part, to dismiss a breach of warranty claim against a drug company. In *Pennsylvania Employees Benefit Trust Fund v. AstraZenca Pharmaceuticals L.P.*, a plaintiff insurance company alleged that the defendant had breached its express warranties by improperly marketing its drug for off-label uses, and, as a result, the plaintiff was forced to expend millions of dollars for medically unnecessary prescriptions. Citing *Iqbal*, the court dismissed the claim because the plaintiff had failed to specifically plead how it had received any direct communication of the express warranties from the defendant: "As the Supreme Court of the United States recently clarified, a federal complaint does not 'suffice if it tenders 'naked assertion[s] devoid of further factual enhancement.'"

In *Frey v. Novartis Pharmaceuticals Corp.*, the U.S. District Court for the Southern District of Ohio discussed *Iqbal* before dismissing plaintiffs' manufacturing- and design-defect claims. "Plaintiffs have done nothing more than provide a formulaic recitation of the elements of a claim under the [Ohio Products Liability Act]," failing to allege any facts that would have permitted the court to conclude that a defect had occurred or that it was the proximate cause of the injuries alleged.

Not surprisingly, members of Congress have taken notice. On July 22, 2009, Senator Arlen Specter (D-Pa.) introduced Senate Bill 1504—the Notice Pleading Restoration Act of 2009—which seeks to limit dismissals under Federal Rules of Civil Procedure 12(b)(6) and (e) to only those complaints that fail to meet the standard set forth in *Conley v. Gibson*, 355 U.S. 41 (1957). *Conley* prohibited federal courts from dismissing a complaint "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim that would entitle him to relief."

In his floor speech, Specter stated that *Iqbal* improperly "expanded upon [precedent] by, to quote Professor Stephen Burbank of the University of Pennsylvania Law School, effectively authorizing federal judges to indulge their 'subject judgments' in evaluating an allegation's plausibility."

Senate Bill 1504 has not yet moved out of the Senate Judiciary Committee.

For the time being, drug and device companies should rely on *Iqbal* to aggressively seek dismissals of "bare bones" complaints, preventing plaintiffs from, as the Court said in *Iqbal*, "unlock[ing] the doors of discovery ... armed with nothing more than conclusions." ■