LJN LAW JOURNAL NEWSLETTERS

Medical Malpractice Law & Strategy®

An ALM Publication

Volume 27, Number 3 • December 2009

The *Iqbal/Twombly* Decisions

Supreme Court's Rulings Mean a Change in Medical Product Trial Tactics

By Kim M. Schmid and William N.G. Barron IV

One of the most frustrating and wasteful legal expenses for a medical device or pharmaceutical manufacturer is the cost of defending against claims where its product is ultimately found not to be involved. This happens where cases are pleaded to include the defendant along with multiple other manufacturers of the same or similar products. Such general pleading tactics in toxic tort cases have become the status quo for many plaintiffs' firms nationwide, where counsel look to "take the easy way out" by simply naming all competing manufacturers of a product rather than doing their investigative homework up front on the issue of product identification. Medical product manufacturers consider this "shotgun" approach to litigation abusive and harassing, and they have long chafed against having to defend against claims that do not involve their products.

Mass Tort Cases

Recently, there has been an uptick in mass tort cases where plaintiffs' counsel, without pleading market-share liability (a theory that is only appropriate in certain, very limited factual circumstances), simply name all

continued on page 6

The Rise of Patient Safety Organizations

Reporting and Sharing Without Fear of Liability

By David S. Ivill and Amy Hooper Kearbey

The 1999 Institute of Medicine (IOM) report, "To Err Is Human," brought patient safety to the forefront with its alarming findings, most jarringly encapsulated in its conclusion that medical error-related deaths in the United States are the equivalent of crashing one jumbo jet per day. L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, eds., "To Err Is Human: Building a Safer Health System" (National Academies Press, 1999). According to the IOM's report, one factor underlying the high rate of medical errors has been a reluctance on the part of providers to identify and address medical errors due to concerns that such information would be used against them in medical malpractice lawsuits or professional disciplinary actions.

The Patient Safety and Quality Improvement Act

The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act or Act) was designed to address this concern by creating a mechanism for the reporting and sharing of patient safety information among providers without the fear of liability. *See* 42 U.S.C. §§ 299b-21–299b-26 (2006). To that end, the Patient Safety Act authorizes the creation of a new type of entity, a patient safety organization (PSO), to receive and analyze information relating to patient safety. The Act confers broad federal privilege and confidentiality protections to this information, referred to as "patient safety work product," with significant penalties for breaches. The PSO program is administered by the Agency for Healthcare Research and Quality (AHRQ) and enforced by the Office of Civil Rights. AHRQ published a final rule implementing the Patient Safety Act in November 2008. *See* 73 Fed. Reg. 70,732 (Nov. 21, 2008). There are currently 69 PSOs listed with the AHRQ.

The Basics

The heart of the PSO process is the patient safety evaluation system, which includes the mechanisms through which information that becomes patient safety work product is collected by the provider and by which the PSO maintains, analyzes and communicates regarding such patient safety work product. *See* 42 U.S.C.

continued on page 2

In This Issue

Patient Safety Organizations 1
The *Iqbal/Twombly* Decisions 1
Med Mal News 5
Certificate of Merit Laws 7
Drug & Device News 9
Verdicts 11
Movers & Shakers . . 12

Iqbal/Twombly

continued from page 1

industry manufacturers of a device when the patient-plaintiff could only have used a singular medical device from one known or knowable manufacturer. Historically, under these circumstances the named defendant manufacturers will each proceed to retain counsel to answer the complaint; exchange some calls and letters demanding evidence of product ID from the plaintiff; conduct sufficient discovery to properly separate the wheat from the chaff (as far as the defense bar is concerned, an objectionable shifting of the burden of proof); and then, finally, after weeks and perhaps even months of legal maneuvering, ultimately seek dismissal of the action because their product is found not to be the one at issue. This scenario, which is repeated frequently in mass toxic tort cases, is an undeniable waste of our courts' time and resources, and constitutes an unjustified expense for those improperly named defendant-manufacturers.

Plaintiffs have benefited for years from this method of proceeding to court. However, plaintiff attorneys who plan to use these tactics should be aware that the defense bar has a friend in two recent U.S. Supreme Court rulings to attack these types of complaints from the outset.

Kim M. Schmid is a partner of the national litigation firm, Bowman and Brooke LLP, where she focuses her practice defending companies in drug and medical device litigation in courts across the country. In addition to her defense litigation practice, she advises her clients on FDA regulatory compliance and reporting requirements. She is located at the firm's Minneapolis, MN, office and may be reached at kim.schmid@bowmanandbrooke.com. **William N.G. Barron IV** is an associate at the firm and concentrates his practice on defending medical device and pharmaceutical manufacturers in cases across the country. He is also located at the firm's Minneapolis office and may be reached at will.barron@bowman andbrooke.com.

In May, the Supreme Court, in *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009), gave defendants a new tool with which to combat generally pleaded complaints against multiple manufacturers. By explaining and extending the reach of *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), the *Iqbal* Court heightened the general pleading standard of Federal Rule of Civil Procedure 8 to a level that arguably requires plaintiffs in medical products liability cases to specifically plead the manufacturer and product allegedly involved. Rule 8(a)(2) requires that in order to state a claim for relief, a pleading must contain a "short plain statement of the claim showing that the pleader is entitled to relief."

Twombly and a Change in Pleading Requirements

Since 1957, federal courts have followed the Conley standard, which interpreted Rule 8 to require plaintiffs only "to give the defendant fair notice of what the claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957).

The 2007 *Twombly* decision abrogates the minimal Rule 8 pleading standard set forth in *Conley*. The *Twombly* court overturned a Court of Appeals' decision and reinstated the ruling dismissing the plaintiffs' complaint, finding that conclusory allegations in support of the elements of a claim were not sufficient to show that the pleader was entitled to relief. *Twombly*, 550 U.S. at 557. The Court explained:

> While a complaint attacked by a 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the "grounds" of his "entitlement to relief" requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. *Id*. at 555 (internal citations omitted).

Twombly, therefore, requires the pleader to make some factual allegations — at least enough, according to the Court, to "raise a right to relief above the speculative level." Naked assertions in a complaint of the elements of a claim, stated the Court, "but without further factual enhancement[,] stops short of the line between possibility and plausibility of entitlement to relief."

Cost saving appears to have been the public-policy driving force behind the Twombly decision. There, the Court alluded to the practical significance of Rule 8, finding that "something beyond the mere possibility of loss causation must be alleged, lest a plaintiff with 'a largely groundless claim' be allowed to 'take up the time of a number of other people.'" *Id*. at 557-58 (quoting *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336 (2005)). The Court intends for basic deficiencies in pleading to "be exposed at the point of minimum expenditure of time and money by the parties and the court." *Id*. at 558. Ultimately, the *Twombly* Court reversed the Court of Appeals finding that plaintiffs did not state enough facts to nudge their claims across the line from conceivable to plausible. *Id*. at 570.

In the immediate aftermath of the landmark *Twombly* decision, courts were divided as to whether the holding applied to all federal cases or whether it applied only in the context of the antitrust subject matter at issue in *Twombly*. In 2009, the Court in *Iqbal* extended *Twombly* to apply to every application of Rule 8.

Ashcroft v. Iqbal and Medical Products Cases

Iqbal advances the *Twombly* decision in two important ways: 1) by clarifying the Court's intention that the *Twombly* pleading standard apply to all federal civil actions; and 2) by setting forth a two-part framework for use in the determination of whether a pleading states a claim. These changes in the way the law is applied have had two effects on medical device litigation.

First, *Iqbal* makes very clear that the heightened *Twombly* pleading standard constitutes the pleading standard for "all civil actions." Much to the benefit of medical device and drug manufacturers, all cases governed by the Federal Rules of Civil

continued on page 8

Iqbal/Twombly

continued from page 6

Procedure now fall within the broad reach of *Iqbal* and *Twombly*. In practice, this may result in yet another factor medical device manufacturers may consider when determining whether to remove select state cases to federal court — the benefit of leveraging cost savings available via an *Iqbal/Twombly* motion to dismiss.

Second, the Court in *Iqbal* set up a road map to aid courts in determining when a litigant has sufficiently stated a claim under the new, heightened standard. The first step in the analysis is to identify any conclusory pleadings. Pleadings that are factually or legally conclusory are not entitled to a presumption of truth and must be supported by well-pleaded factual allegations. "Threadbare recitals of the elements of a claim, supported by mere conclusory statements, do not suffice." *Id*. at 1949 (citing *Twombly*, 550 U.S. at 555). The second step in the analysis, where a pleading does contain well-pleaded factual allegations, is to "assume their veracity and determine whether they plausibly give rise to an entitlement to relief." *Id*. at 1950. The *Iqbal* Court said, "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id*. at 1949. The Court went on to state that the standard for plausibility "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id*. (citing *Twombly*, 550 U.S. at 556.)

Applying this test to the facts in *Iqbal*, the Court determined that the plaintiff had not "nudged his claims of invidious discrimination across the line from conceivable to plausible." *Id*. at 1950–51. The Court found that the formulaic recitation of the elements of a constitutional discrimination claim did not trigger an assumption of truth. For instance, the Court determined that the following statements, as pleaded by the plaintiff, were conclusory: "Ashcroft was the 'principal architect'" and "petitioners knew of, condoned, and willfully and maliciously agreed to subject [him] to harsh conditions … solely on account of [his] religion, race, and/or national origin." *Id*. Therefore, the Court concluded, the *Iqbal* plaintiff did not meet his burden on several elements, and his claims were properly dismissed.

Recent Defense Successes Applying *Iqbal/Twombly*

Medical device and pharmaceutical defendants have only begun to reap the benefits of the new *Iqbal/Twombly* pleading standard. Indeed, since the Supreme Court decided *Twombly* in 2007 and *Iqbal* in May 2009, several federal district courts have already granted manufacturers' motions to dismiss. This trend is likely to continue in favor of similarly situated defendants.

For instance in *Wolicki-Gables v. Arrow Int'l, Inc*., Not Reported in F.Supp.2d, 2008 WL 2773721 (M.D. Fla. June 17, 2008), the plaintiff did not specifically identify the "implantable drug delivery system" it alleged caused plaintiff's injury. As to negligence, defendants argued that the existence of a duty was not sufficiently pleaded where there was no factual basis that identified a relationship between the defendants and the product. The *Wolicki-Gables* plaintiff conceded the point and asserted that it had documents that would allow it to identify the product. In light of this, the court dismissed the plaintiff's claims, granting leave to amend to specifically identify the medical device in question. The court came to the same result with regard to the plaintiff's strict liability claim, finding that "the occurrence of symptoms without more [factual allegations], does not plausibly suggest a defect."

Similarly, in *Sherman v. Stryker Corp*., Not Reported in F.Supp.2d, 2009 WL 2241664 (C.D. Cal. Mar. 30, 2009), a pain pump case in which the plaintiff alleged that she developed glenohumeral chondrolysis, the court dismissed all claims against AstraZeneca, Hospira, and Abbott Laboratories because the plaintiff did not allege the names and types of medications administered. The court found that the plaintiff merely generally alleged that she received doses of "anesthetics," "anesthetic drugs," and "pain relief drugs," so it dismissed the claims against AstraZeneca, Hospira, and Abbott with prejudice, holding that plaintiff had not alleged enough facts to show causation or liability. In fact, at most, the plaintiff alleged that the defendants where a handful of the many manufacturers that made medications that could have been administered to plaintiff. The court also dismissed the plaintiff's claims against pump manufacturer Stryker and allowed the plaintiff 20 days to re-plead claims against that defendant.

Most recently, in *Dittman v. DJO LLC*, Slip Copy, 2009 WL 3246128 (D. Colo. Oct. 5, 2009) — another pain pump case in which the plaintiff alleged that she developed chondrolysis — the court dismissed all claims against AstraZeneca and Abbott Laboratories where the plaintiff again failed to allege the names and types of medications allegedly administered through the pain pump. The court determined that the plaintiff, in not naming a specific product and in failing to allege that the defendants' products were actually used, had not sufficiently alleged that the products could have caused his injury. The court went on to find that:

> This deficiency is fatal to the claim. Plaintiff has no facts, only speculation, on which to base his claim that defendants' products caused or contributed to his injury. This mere possibility, *i.e.*, that the medicine used could have been made by these defendants, rather than by any number of other manufacturers of anesthesia drugs, is not adequate to state a claim under the prevailing standards as set forth by *Twombly* and *Iqbal*. *Id*.

The court dismissed the plaintiff's claims against these defendants

continued on page 10

Drug & Device News

continued from page 9

than those who forego medication to reduce pain and fever post-vaccination. Prymula, Roman, M.D., et al., Effect of Prophylactic Paracetamol Administration At Time of Vaccination on Febrile Reactions and Antibody Responses in Children: Two Open-Label, Randomised Controlled Trials. *The Lancet*, Vol. 374, Issue 9698, pp. 1339-1350, 17 October 2009. The researchers' theory for why children given medications on a prophylactic basis following inoculation get less protection from their vaccines is this: The immune response produces fever, and without that fever the body is less able to produce the antibodies that build resistance to disease. The study's authors recommend that medical care providers stop routinely telling those receiving vaccines to take fever-reducing medications immediately following inoculations. Such medications should be taken only when necessary, they say.

Byetta Label Changes Highlight Possibility of Kidney Problems

Acting on new safety information about possible kidney function problems associated with the use of Type-2 diabetes drug Byetta, the FDA and the drug's manufacturer have updated Byetta's label. The move came after the FDA received 78 reports of problems with kidney function in patients using the drug. "Health care professionals and patients taking Byetta should pay close attention to any signs or symptoms of kidney problems," said Amy Egan, M.D. M.P.H., of the Division of Metabolism and Endocrinology Products at the FDA's Center for Drug Evaluation and Research. "Patients also should be aware that problems with kidney function could lead to changes in urine color, frequency of urination or the amount of urine, unexplained swelling of the hands or feet, fatigue, changes in appetite or digestion, or dull ache in mid to lower back." Label change information can be found at: http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm188656.htm.

—❖—

Iqbal/Twombly

continued from page 8

without express leave to replead.

Application of the *Iqbal/Twombly* Standard to Future Pleadings

An *Iqbal/Twombly* motion will not be appropriate in every case, but where applicable, it is likely to be deftly used as a sword by the defendants to stop a pleading practice that has plagued their legal departments in the past. The key to a medical product manufacturer's winning the dismissal of form complaints that allege liability against multiple defendants under the *Iqbal/Twombly* standard will be in their leaning heavily on the plaintiff's conclusory, formulaic statements and the lack of product identification.

Form complaints that are used serially in mass toxic tort matters and transferred from counsel to counsel are general by nature, so that they can be adapted to each case in any jurisdiction. In most instances, such complaints only very generally outline the elements of some or all of the causes of action alleged. Pleadings of this type were sufficient under the old *Conley* pleading standard, and plaintiffs mistakenly continue to fall into this trap, especially in the context of mass tort litigation. However, under *Iqbal/Twombly*, a formulaic and conclusory recitation of the elements of negligence, strict liability, or breach of warranty claims, as commonly seen in medical products litigation, is insufficient to state a claim for relief. Plaintiff attorneys should now take note of the possibility that courts will look for something more than the elements of a claim, and if the plaintiff does not allege any well-pleaded facts in support, such a claim is susceptible to a 12(b)(6) attack.

Of course, there is no guarantee that all *Iqbal/Twombly* 12(b)(6) motions will prove effective for medical product manufacturers, because of the recent and still evolving nature of this area of the law. Each judge will decide on a case-by-case basis whether a complaint states enough factual material to be "plausible." And it may be rare that a judge will dismiss a complaint with prejudice. Defendants, however, can consider dismissal of complaints with leave to amend and plead more specific facts a victory. Re-pleading will shift costs currently expended by defendants back onto plaintiffs, and force plaintiffs to conduct the necessary investigation, pre-suit, regarding product identification. Defendants in inadequately pleaded cases may now be able to extricate themselves instantly from cases in which their product is not at issue, without the costs associated with discovery. Granted, such a motion will still constitute a cost to manufacturers, but in cases where plaintiff does not plead product identification and refuses informal requests for product identification, a Rule 12(b)(6) motion will be much more cost effective than engaging in the often long and winding road of serving written discovery to obtain product ID documents. As a practical matter, co-defendants may even split the costs of an *Iqbal/Twombly* motion, reducing defense costs even further.

Where plaintiffs allege that every manufacturer in the industry made the one device used by plaintiff, the case is perfectly suited to bring a Rule 12(b)(6) motion to dismiss for failure to state a claim. The availability of the new *Iqbal/Twombly* motion practice strategy should alert plaintiffs' counsel who have become comfortable with filing dozens, if not hundreds, of "shotgun" complaints, to think twice before sticking to the status quo.

—❖—