Four More Reasons To Love Twlqbal

Thursday, August 25, 2011

Bexis was away on vacation last week. When he returned, he found four more reasons why we (on the defense side) should love Twlqbal. These four opinions have been duly added to our Twlqbal Cheat Sheet, but they deserve more mention than that:

Maybe An Advisory Opinion – But A Good One

In Leonard v. Medtronic, Inc., 2011 WL 3652311 (N.D. Ga. Aug. 19, 2011), the court Twlqballed everything that conceivably could have been considered a "parallel violation" claim in a PMA medical device case. A plaintiff can't get away with a bare allegation that the defendant "did not satisfy the Food and Drug Administration's Pre-Market Approval standards for the devices." Id. at *2. Rather, a plaintiff must "specify [the] particular federal standard the manufacturing process violated" and "state how [defendant] violated that standard." Id.

"In considering whether the plaintiffs had raised a parallel claim . . . a plaintiff cannot simply incant the magic words that a defendant has violated federal regulations. Rather, the parallel claims must be specifically stated in the initial pleadings and the plaintiff must allege that the defendant violated a particular federal specification concerning the device at issue. To properly allege parallel claims, the complaint must further set forth facts pointing to specific [pre-market approval] requirements that have been violated. In short, a bare allegation, devoid of factual detail, that [defendant] did not satisfy the FDA's Pre-Market Approval standards for the device is insufficient to satisfy the requisite elements of a parallel claim."

Id. at *5. That's an excellent result in and of itself, but there's more.

Causation must also be pleaded – with facts establishing how the defendant's "alleged noncompliance with the FDA premarket approval standards caused [plaintiff] harm." Leonard, 2011 WL 3652311, at *2; see id. at *6 (collecting causation cases and criticizing Hofts v. Howmedica Osteonics Corp., 597 F.Supp.2d 830, 840–41 (S.D. Ind. 2009)). The plaintiff in Leonard needed a lot more than the boilerplate he pleaded:

"Once the complaint's conclusory statements and formulaic recitations are excluded, the terse factual allegations contained in the complaint do not satisfy Supreme Court standards. . . . There is no allegation

that the [device] improperly fired during the [alleged] incident or that the [it] injured [the decedent] at that time. In fact, the complaint never alleges that [the device] malfunctioned at any time. Although the complaint alleges that [decedent] died as a result of [the device], the complaint fails to disclose when [he] died, why he died, or how his death in any way relates to [the device] or [the defendant's] actions."

Id.

Nonetheless, because the plaintiff sought to file an amended complaint, the court denied the defendant's motion to dismiss without prejudice. Id. at *12. It's a sort of strange way of winning by losing. If the plaintiff's amendment doesn't meet the Twlqbal standards laid out by the court, we expect to see Leonard dismissed.

Twlqbal And Judicial Notice, Perfect Together

Another goodie is Salvio v. Amgen, Inc., No. 2:11-cv-00553, slip op. (W.D. Pa. Aug. 18, 2011), which Twlqballed a wrongful death action in a prescription drug case with no preemption overtones. Of most interest is Salvio's treatment of the plaintiff's warning claim (the most important allegation in most such cases), because it involved another topic we've been watching – judicial notice of publicly available (often FDA) documents.

"To resolve a Fed. R. Civ. P. 12(b)(6) motion, a court may generally consider the allegations in the complaint, along with any exhibits attached to the complaint and matters of public record." Salvio, slip op. at 7 (citations omitted). The plaintiff had referenced the drug's warnings in the complaint, the defendant helpfully attached the actual package insert to its motion papers, and nobody disputed the authenticity of the document. Id. at 8. Thus, "the Court will consider the Package Insert in ruling on Defendants' motion to dismiss." Id.

Boy, did the court consider it.

The plaintiff's negligence count was the usual "vague laundry list of fifteen (15) generalized alleged breaches of duty." Salvio, slip op. at 8. Pennsylvania follows the learned intermediary rule, id. at 9-10, so in pleading any warning claim, a plaintiff must plead how the alleged warning defect affected the prescribing doctor. Id. at 9, 11. The plaintiff didn't come close to doing this. In the first place, he didn't describe the alleged defect at all:

"Other than a vague reference that the FDA demanded a "strengthened" black box warning . . ., Plaintiff does not describe the alleged failure-to-warn. Plaintiff also does not describe the differences between the "black box" warning on the [drug's] package before and after the FDA's demand. Nor does Plaintiff plead sufficient facts about the timing of Decedent's use of [the drug], the onset of her [injury], or ***how the alleged distinctions in the warnings would have had a causal effect****."*

Id. at 10 (emphasis added). That's good stuff right there – most complaints suffer similar deficiencies – before we ever get to the package insert.

It turned out that the drug's warning, even before the alleged black box change, discussed the precise injury that the plaintiff alleged repeatedly, specifically and in bold-faced, capital letters. Salvio, slip op. at 10-11. The actual warnings – judicially noticed – "appear[ed] to . . . contradict[]" the boilerplate allegations of inadequate warnings that were in the complaint. Id. at 11. Thus, in a case where the package insert actually discusses the plaintiff's alleged injury, the plaintiff must, at the pleading stage, provide facts that plausibly establish how some warning inadequacy affected the plaintiff's treatment so as to cause injury:

"At a minimum, Plaintiff has failed to plead facts regarding how this warning was not reasonable. Plaintiff has also failed to plead facts showing that Defendants did not properly discharge their duty by warning Decedents physician through the Package Insert or otherwise. He has also failed to provide any facts about how the change in the "black box" warning affected her choice to either continue taking [the drug], or stop taking it. Without these facts, the Plaintiff cannot sufficiently state a cause of action for lack of both breach of duty and causation. Thus, Plaintiff fails to state a claim for negligent failure-to-warn."

Salvio, slip op. at 11-12. Thus, Twlqbal's requirement that plaintiffs plead facts rather than conclusory boilerplate, combined with judicial notice of the actual warnings, allowed the defendant to demolish the warning claim in Salvio at the pleading stage.

Salvio thus holds that, to plead a viable claim, plaintiffs must allege facts addressing the twin issues of adequacy of the warning and warning causation. Plaintiffs cannot escape Rules 8 and 12 with boilerplate and by omitting the actual warnings. Rulings such as this will weed out implausible claims (the real purpose of Twlqbal) by requiring plaintiffs actually to investigate their claims a bit before filing. Shades of Rule 11!

Good plaintiffs' lawyers can, and will if required, do this, and defendants need to be prepared for the consequences – in particular an increase in *ex parte* communications between plaintiffs' counsel and prescribing physicians. However, with so many bad cases out there, on the whole we can't be anything but pleased with Twlqbal as a more efficient way of getting rid of them. Now if we can just get the MDL judges to follow the law….

There's other good stuff in Salvio, particularly if you practice at all in Pennsylvania (as we do). (1) There are no recognized claims for failure to test or negligent marketing. Salvio, slip op. at 8-9. (2) Plaintiff failed to plead an alternative design in her boilerplate negligent design claim. Id. at 12 ("baldly stating that there are safer alternatives to [a drug], without providing factual support that they exist, is insufficient to survive a 12(b)(6) motion"). (3) Pennsylvania doesn't allow any strict liability claims in prescription medical product liability litigation. Id. at 13-15. (4) Pennsylvania doesn't allow express or implied warranty claims in prescription medical product liability litigation. Id. at 15-16. (5) Punitive damages are not available without a viable substantive claim, and in any event, no facts suggesting "outrageous" conduct were pleaded. Id. at 16-17. (6) Ditto for wrongful death/survival – there must be a viable substantive claim. Id. at 17-18.

Finally, plaintiff was granted leave to amend (negligence only) in Salvio, slip op. at 18-19. A second bite at the apple is more or less a plaintiff's right at the Rule 12 stage. We'll have to see, in light of the judicially noticed warning, if the plaintiff is able to come up with plausible facts that a different warning would have materially changed the physician's conduct.

Twlqbal Applies To Claims Based Upon Comment K

In Rollins v. Wackenhut Services Inc., ___ F. Supp.2d ___, 2011 WL 3489442, slip op. (D.D.C. Aug. 10, 2011), the plaintiff's suicide claim was Twlqballed (this one was judgment on the pleadings, but Twlqbal applied, 2011 WL 3489442, at *4). The first two-thirds of the opinion dealt with the plaintiff's weird (a negligent hiring claim brought on **behalf** of the person who was allegedly negligently hired?) claims against the decedent's employer, but after disposing of those, Rollins turned to the drug-related claims.

After the boilerplate was disregarded, see 2011 WL 3489442, at *9, the court agreed that the drug-related claim in the complaint was "nothing more than that [the decedent] took [the drug]

and months later committed suicide." Id. There were no manufacturing or warning (odd) claims pleaded at all:

"There are no facts alleged that would appear to relate to manufacturing defects in the [drug] doses taken by [the decedent], and, regarding the failure to warn claim, the Complaint's allegations state only that [drug] ***did*** *carry an FDA-mandated "black box warning" regarding suicide risk."*

Id. at *10 (emphasis original). Off-label promotion allegations were disregarded in the absence of any facts suggesting any off-label use in the case. Id. at 10 & n.8. So were other promotion-related claims, where no facts tied them to the plaintiff's particular prescriber. Id. at 11 n.9.

Presumably because of the black box warning, Rollins seems to have been primarily a design defect case. That wasn't properly pleaded either. "To prevail on a design defect claim, the plaintiff would have to show the risks, costs and benefits of the product in question and **alternative designs**, and that the magnitude of the danger from the product outweighed the costs of avoiding the danger." Rollins, 2011 WL 3489442, at *10 (emphasis added). The drug was a comment k product, and the complaint failed to plead the elements of a comment k claim:

"The Complaint here does not allege that the pharmaceutical defendants failed to properly prepare [the drug] or failed to include proper directions and warnings. Even if the plaintiff were to argue that Comment k is inapplicable here, the Complaint does not contain any specific allegations to suggest that the risks, costs and benefits of the product in question and ***alternative designs****, and that the magnitude of the danger from the product outweighed the costs of avoiding the danger.* ***The Complaint does not allege that the risks of [the drug] outweigh its benefits or that there was any equally effective alternative design or manner of increasing the safety of the product.*** *Indeed, the Complaint does not attempt to identify what about [the drug] made it "defective," other than its "known risks of increasing suicidality in certain patients" – a danger that the plaintiff admits was specifically described in the drug's FDA-mandated warning materials."*

Id. at 11 (emphasis added). Thus, Rollins, like Salvio, stands for the proposition that, if a plaintiff is going to pursue a non-warning claim, that plaintiff had better allege facts establishing a safer alternative design – and not just some different drug.

Twlqbal And The Peripheral Defendant

In Mills v. Bristol-Myers Squibb Co., 2011 WL 3566131, slip op. (D. Ariz., Aug. 11, 2011), the drug-related claim seems to have been a "throw in." The "facts" – if they can be called that – pertinent to this claim "are set forth in just one paragraph of the 123 paragraphs" of the complaint. Mills, 2011 WL 3566131 at *1. Twlqbal to the rescue. More than an alleged injury following a prescription is required:

"This does not allege how the product itself is defective, it only alleges the harm plaintiff suffered after taking [the drug], which may or may not have been caused by the drug. Plaintiff should plead more specific facts about how [the drug] is defective and how it was the proximate cause of her particular injury."

Id. at *2. The plaintiff's warning claim was particularly deficient:

"As for the failure to warn claim, plaintiff must show that the product was defective because it contained an inadequate warning. Plaintiff does not plead any facts about what the [drug] label said or how it was deficient. Moreover, the warning did describe [the risk the plaintiff claimed]."

Id. at *3. As in Salvio, the court took judicial notice of the actual package insert. Id. at *3 n.2 ("[w]e may consider the [drug] label attached as an exhibit to defendants' motion to dismiss, because it is a matter of public record").

In addition: (1) the terms of any express warranty weren't pleaded at all. Mills, 2011 WL 3566131, at *3 n.3. (2) "Outrageous" conduct sufficient to plead emotional distress wasn't pleaded because the nature of the allegedly "withheld" information wasn't stated. Id. (3) If plaintiff wants to amend, she must present an amended complaint. Id.

* * * *

That's four – count 'em, four – excellent Twlqbal decisions in little over a week. As Twlqbal discusses, the early dismissal of weak claims is essential to prevent defendants from being forced to settle lousy claims simply due to the expense of discovery. While some of these plaintiffs might come back with something plausible, we doubt they all will. It's easy to plead boilerplate, and much harder to plead plausible facts – especially in cases (Salvio, Rollins, and

Mills) where the package insert specifically mentions the alleged risk, or in cases (Leonard) where preemption limits the types of available claims. In such cases, defendants would be well-advised to hold plaintiffs to their pleading obligations under TwIqbal, and to employ judicial notice to get undisputed facts that the plaintiffs would rather ignore before the court.