Twlqbal, And Moore

Friday, October 14, 2011

We found the decision in Mills v. Bristol-Myers Squibb Co., 2011 WL 4708850 (D. Ariz. Oct. 7, 2011), interesting for at least three reasons. First of all, it's another Twlqbal dismissal, so it goes on our Twlqbal cheat sheet.

But what's even more interesting is precisely what the plaintiff wasn't able to plead. The plaintiff claimed injury from an anti-clotting drug because, "'[u]pon information and belief,' [plaintiff] is a CYP carrier." 2011 WL 4708850, at *2. While Twlqbal doesn't bar information and belief pleading outright, Mills holds that such pleading can't be used where the information is equally available to the plaintiff. That the plaintiff was apparently unwilling to pay for her own genetic testing didn't cut it under Twlqbal:

> "This is not a case where the facts are in the sole possession of the defendants. Plaintiff's genetic makeup is a fact solely within her control. . . . Neither does her belief that she carries the CYP variant make an inference plausible. According to plaintiff, approximately thirty percent of Caucasians possess the CYP variant. This means that about seventy percent do not."

Id. at *2. So Twlqbal forces the plaintiff has to put up or shut up, that it, actually get herself tested. She can't plead that she might have a condition, only that she does have it. Here, here - that's part of (or should be part of) pre-complaint investigation of potential claims.

Plaintiff in Mills also claimed injury due to a purported synergistic effect of the defendant's drug. 2011 WL 4708850, at *2. She relied upon a particular medical study to make this claim. But her pleading showed that she didn't have either: (1) a characteristic of the study participants (a stomach ulcer) or (2) the injury the study studied (stomach bleeding). Id. Therefore, that "study does not show what may be defective about [the drug]." Id. So if a plaintiff is going to assert a study in the complaint, there better be some facts suggesting that the study is relevant to that plaintiff's claim.

Moreover, just pleading "defect" is not enough where state law (Arizona, in the Mills case) also requires that the defect be "unreasonably dangerous." 2011 WL 4708850, at *2. Here's where the second interesting aspect - something that's not Twlqbal - of the Mills decision comes into

play. The court holds that, in a prescription drug case, Arizona would apply the definition of design defect used by the Third Restatement of Torts §6(c), which is:

"A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients."

2011 WL 4708850, at *3 (quoting from the Restatement).

In and of itself, that's notable, since §6(c), as we've discussed before, hasn't met with a very hospitable reception in the courts – particularly in drug (as opposed to medical device) cases. But Arizona is one of the few jurisdictions where courts have been willing to adopt the limited design defect claim recognized by the Restatement. Our thinking on whether that's a good or bad thing varies, depending on whether the claim involves a device (good, since §6(c) is tougher than the usual safer alternative design standard, and devices often have alternative designs) or a drug (bad, since it's almost impossible for design defect claims against prescription drugs to meet the existing alternative design standard). Since Mills involves a drug, it would fall on our "bad" side as a theoretical matter.

But anyway, back to Mills. The court threw out the plaintiff's design defect claims under the Third Restatement "any class of patients" standard because her allegations were inherently incompatible – those being that the drug was hazardous to a minority of patients who carried a certain "genetic variant allele." 2011 WL 4708850, at *3. Where, by definition, the drug was only hazardous to a subgroup, and thus could readily be prescribed to everyone else, a Restatement Third design defect claim could not be stated. Id.

The plaintiff's warning claim in Mills was also Twlqballed. Under the learned intermediary rule, to plead causation in a warning case requires some allegation that "had a proper warning been given, the injury would not have happened." 2011 WL 4708850, at *3. Proper case investigation in this context requires that the plaintiff actually contact the prescriber about the case, since a mere "information and belief" allegation that the prescriber would not have prescribed the drug had s/he been properly warned doesn't cut it:

> We noted in our dismissal of the [initial complaint] that plaintiff "could have contacted her physician" to determine facts that were not solely in the control of defendants. Plaintiff has not done so.

Id. This ruling is important, particularly since defendants in many jurisdictions are precluded from informally contacting a plaintiff's prescribers. Requiring that plaintiffs plead actual facts suggesting a causal effect of a different warning on their prescribers' actual treatments is an excellent application of Twlqbal.

So that's two.

What's the third interesting thing about Mills?

That would be the nature of the plaintiff's claim itself. The plaintiff is claiming that a drug is defective, not because of anything inherent in the drug itself, but solely because it is less effective (and therefore has a different risk-benefit profile) due to the **plaintiff's peculiar genetic makeup**. Essentially, the allegations seek to impose a non-FDA-approved contraindication, using state law, based upon human genetic variability. With advances in computer technology making genetic testing exponentially cheaper and more detailed as times passes (see Moore's law), more and more genetic variability in the efficacy of prescription drugs is bound to be discovered. Eventually - certainly within some of our lifetimes - we'll be able to carry our entire individual genetic code around with us on a chip, should we so choose.

We've blogged before about the dangers of allowing racially-based "defect" claims against prescription drugs. But the allegations in Mills are, if anything, worse, since Mills alleges directly what the race-based claims could only get at indirectly. As we said in that prior post, "[r]acial-ethnic categories are blunt instruments for getting at what seems to be the real issue reported in the labels, genetic susceptibility." The complaint in Mills is a bare genetic susceptibility claim, frankly based on an allegation of "variant" genetic characteristics shared by only a minority of the population.

In our view, unless and until – and only to the extent that – the FDA decides to assess drug approvals and contraindications on the basis of genetic subgrouping, this type of tort claim should not be recognized, because it is flatly contrary to the criteria by which the intended uses of drugs are currently determined. Claims such as in Mills, which are at loggerheads with FDA criteria for drug development, are precisely those with the most potential for making

pharmaceutical manufacturers into “sitting ducks” for litigation, in this instance litigation based on extraneous genetic factors.

It may well be that the coming (and to some extent existing) revolution in genetically individualized medical therapy will require changes in how drugs are evaluated, labeled, *etc*., but this is a singularity-driven issue that needs to be addressed by the policy branches of our government, and not haphazardly in product liability litigation.