Mensing and Twlqbal Team Up To Deliver a Knockout

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We know sports-courtroom analogies are overused, hackneyed, timeworn, trite (you get the idea). But, nevertheless they can be useful and provide a little color to what might otherwise be viewed by some (of course, not us) as dull legal goings on. For instance, we could simply report that the District of Maryland tossed out another case against a generic prescription drug manufacturer. Grinage v. Mylan Pharmaceuticals, Inc., 2011 U.S. Dist. Lexis 149667 (D. Md. Dec. 30, 2011). Or we could say –

A four-round hard glove fight took place in at 101 W. Lombard Street, Baltimore in the final days of 2011. The fight pitted local Beatrice "the Plaintiff" Grinage against West Virginia's own Mylan "the Defendant" Pharmaceuticals. Catherine C. Blake, United States District Judge acted as referee. The stakes were Grinage's claim for the wrongful death of her husband allegedly caused by his ingestion of generic Allopurinal. From the minute the bell rang, it was evident that the Defendant, with the law on its side, had the reach advantage. In the first round, the Defendant had Grinage reeling from a right uppercut. In the second, the Defendant's left jab, right cross combination almost finished the Plaintiff off. The Plaintiff hung in for two more rounds, but the devastating blows from the prior rounds had taken the wind from the Plaintiff's sails. With one last hook, the Plaintiff went down; the bell rang and Mylan emerged victorious. And the crowd went crazy!!

OK, back to reality. The punches were really Mensing and Twlqbal and they were as effective as any roundhouse and equally impervious to all plaintiff's bobbing and weaving.

Round One – Failure to Warn: Plaintiff tried to dodge Mensing by arguing efficacy over substance. If claims regarding the substance of the generic drug warning are preempted, plaintiff claimed that generic drug manufacturers should have tried to harder to provide the warning they were allowed to give. Grinage, 2011 U.S. Dist. Lexis 149667, *10. Plaintiff argued that the defendant should have "employed more effective communication to healthcare providers and consumers" through things like Dear Doctor letters, training programs and public notifications. Id. To be clear, plaintiff's contention was that the defendant could have met its duty to warn by using these methods of communication "*without* including substantial new

warning information." Id. at *12. However, even if Mensing leaves open for consideration a claim for "effective communication," you still have to plead causation:

"Here, there is no allegation that [plaintiff] and his doctor did not see the labeling as it was approved and take into consideration the information included therein . . . . Nor has [plaintiff] alleged any other facts sufficient to support a reasonable inference that further communications consistent with the approved label would have affected the choices made by [plaintiff] or his doctor."

Id. at *13. Down goes failure to warn.

Round Two – Defective Design: This is where Mensing and Twlqbal work a really effective combo. Maryland state courts are divided over whether the proper test for determining if a prescription drug is defectively designed is risk-utility or consumer expectation. The latter fails under Mensing:

"An ordinary consumer forms her expectations regarding the safety of drugs from her doctor or from the drug's label. Thus, if [a drug] is dangerous beyond the expectations of the ordinary consumer, that can only be a symptom of [the manufacturer's] failure to update its label or communicate effectively with doctors. For reasons articulated above, any state law defective design claim predicated on this theory is pre-empted by FDA labeling regulations."

Id. at *18. But plaintiff's design defect claim couldn't be helped by application of the risk-utility test because she failed to plead any facts regarding the utility of the drug or the availability of less dangerous alternatives. In steps Twlqbal. "Here, no factual allegations are included that raise the right to relief on a risk-utility design defect theory above the speculative level." Id. at *19. Down goes design defect.

Round Three – Breach of Implied Warranty: With the plaintiff on the ropes, the breach of warranty claims topple over with very little resistance. First, a breach of warranty of merchantability requires proof of the existence of a defect. Id. at *20-21. See rounds one and two. Second, a breach of warranty of fitness for a particular purpose requires an allegation of a particular purpose "as distinguished from the ordinary or general use to which the goods would be put by the ordinary buyer." Id. at *21. No such allegation means no such claim. Down goes breach of warranty.

Round Four – Fraud: Plaintiff is staggering and it doesn't take much to secure the knockout. Fraudulent representations allegedly made to the plaintiff or his doctor – preempted under Mensing. Id. at *22-23. Fraudulent representations allegedly made to the FDA – insufficiently pled to meet the heightened requirements of Rule 9(b):

"The complaint contains no reference to any specific communication to the FDA that constituted a misrepresentation, or to any specific studies or other information improperly omitted from filings or other communications with the FDA."

Id. at *23-24. And, we would argue this fraud claim is also preempted by Buckman, but we'll settle for a Rule 9 dismissal. Down goes fraud.

Another bout goes in the books in favor of generic drug manufacturers. Thanks to Adam S. Ennis at Jackson Kelly PLLC for passing this one along.