

OPPENHEIMER

OPPENHEIMER WOLFF & DONNELLY LLP

# THE PREEMPTION PLEADING CONUNDRUM

*David P. Graham  
Oppenheimer Wolff & Donnelly  
for MSBA*

Plaza VII, Suite 3300  
45 South Seventh Street  
Minneapolis, MN  
55402-1609  
t: 612.607.7000  
f: 612.607.7100

# Pleading challenges since *Twombly/Iqbal*: preemption and pleading parallel claims

# Where Are We Now?

- » Circuit split as it relates to parallel claims – on October 31, 2011 U.S. Supreme Court declined review, in *Stryker v. Bausch*, U.S. No. 11-2, review denied (10/31/11)
  - Device-specific pleading required – 8th, 11th and 5th Circuits
  - Less specific or sliding-scale pleading required – 7th and 6th Circuits

# Impact

- » Evidence of impact of *Twombly/Iqbal* change?
  - Empirical analysis showed an initial increase in granting of 12(b)(6) motions after *Iqbal*, but with leave to amend in more cases
    - » Some literal application of the “two-pronged” approach.
      - Legal conclusions not accepted as true
      - Must state a “plausible” claim for relief
  - Also evidence of use of “judicial experience common sense” only approach

# Analysis

- » Analysis by Patricia W. Hatamyar, The Tao of Pleading: Do *Twombly* and *Iqbal* matter Empirically? 59 Amer. U.L. Rev. 553, 583 (2010)
- The percentage of motions granted in tort cases increased from Conley (40%) to *Twombly* (46%) to *Iqbal* (52%).
  - Slight decrease in motions granted without leave to amend Conley (40%) to *Twombly* (39%) to *Iqbal* (37%).
  - Increase with leave to amend – 6% under Conley to 9% under *Twombly* to 19% under *Iqbal* – most statistically significant a factor of 4.04 – or seven times more likely.
  - Percentage of mixed rulings declined to 25% under *Iqbal* from 28% under Conley.

# Analysis (cont.)

Overall it appears that 12(b)(6) motions are granted at a similar rate than before *Twombly* – many with leave to amend.

# Analysis of Drug and Device Cases

Analysis by William M. Janseen, “*Iqbal* Plausibility” in Pharmaceutical and Medical Device Litigation, 71 La. L. Rev. 541 (2011)

- » 264 Drug and Device Case Cohort – Data through August 2010
- » 21% of the cases impacted by *Iqbal* – “conclusions-do-not-count” principle cited
  - 29 of 56 cases granted leave to amend
  - 27 of 56 cases court not concerned about information asymmetry
- » Percent of cases impacted by *Iqbal* dropped after the first 3 months post-*Iqbal*
- » 79% of courts view *Iqbal* as not particularly impactful?

# Paradoxes

Courts do not require “heightened specificity,” but “conclusions” are unacceptable. Never mind that if the pleader is concerned that an allegation is “conclusory,” she would probably attempt to remedy it by making the allegation more specific.

# Paradoxes

Plaintiffs must allege “facts,” but they need not be “detailed facts.”

# Paradoxes

Courts may or may not be required to construe the complaint in the light most favorable to a plaintiff, but courts certainly cannot grant a plaintiff “unwarranted” inferences of fact.

# Paradoxes

Courts are not to weigh evidence, evaluate witness credibility, or judge the likelihood that a plaintiff will prevail at trial, but a plaintiff's claim must be "plausible on its face" in light of the judge's "judicial experience and common sense."

# Paradoxes

Courts should construe a complaint as a whole, and should not take any one statement in isolation, but if a court deems an allegation to be “conclusory” under some undefined standard, then the allegation may be ignored.

# Identifying What Type of Preemption

- » Express – statutory language
- » Implied – structure and purpose of federal law
  - Field – pervasive legislation
  - Conflict – dual compliance an impossibility

# Strategies for Winning Preemption Motions to Dismiss

1. Understand your judge and jurisdiction
  - » What the judge will require from plaintiffs to get through “narrow gap”.
  - » Will the judge allow amendments? How many?
  - » Will the judge allow discovery?

# Strategies for Winning Preemption Motions to Dismiss

2. What claims are being made?
  - » Manufacturing defect claims
  - » Breach of warranty claims
  - » Claims involving off-label promotion
  - » Warning and design claims

# Strategies for Winning Preemption Motions to Dismiss

3. What evidence do plaintiffs have?
  - » FDA action and letters based on specific regulatory violations?
  - » Dear Doctor letters
  - » Accurate device identification?
  - » Are plaintiffs merely repeating the legal elements?

# Strategies for Winning Preemption Motions to Dismiss

4. Important elements of a successful motion
  - » No specificity in pleadings
  - » No facts to connect the alleged harm with a specific device defect
  - » No specific regulatory violation
  - » No state-law analogue – such claims prohibited under 21 U.S.C. 337(a) as a prohibited private FDCA cause of action (not all states permit negligence per se claims)