



*FTC v. Watson Pharmaceuticals:*  
How Should Courts Analyze  
“Pay-for-Delay” Settlements?

Randall Hack  
Chicago, IL

Chuck Loughlin  
Washington, D.C.





# The Big Picture

- Prescription drugs comprise expanding share of therapeutic treatment
- Micro-therapy assures trend continues
- 2011 -- \$245 billion; 4 billion scripts
- Generics account for 80% of \$\$\$
- If head-to-head with brand, generic purchased 90% of time





# The Hatch-Waxman Act

- Streamlines generic drug application and approval process
- Brand manufacturer applies for NDA
- Demonstrate safety and efficacy
- Generic manufacturer applies for ANDA
- Bioequivalence
- First ANDA-filer gets 180 day exclusivity



# Economics of Generic Entry

- First generic enters at modest discount
- Captures over half of sales in first year
- Subsequent generic entry drives pricing to 15% of pre-generic price
- Generics ultimately capture 90% of sales
- Incentive to delay or preempt generic entry
- Prozac -- \$2 billion savings from early entry





# Paragraph 4 Certification

- Generic manufacturer certifies that patent is *invalid* or *would not be infringed*
- Orange Book notification
- Paragraph 4 certification a technical act of patent infringement
- Brand files infringement action
- 30 month automatic stay



# Reverse Payment Settlements

- Litigation costly and often uncertain
- Existential business risks
- First ANDA-filer settles by agreeing to “early” entry date with brand making substantial payment to generic
- Is the payment for delaying generic entry or for something else?





# Theory of Competitive Injury

- Buys protection for weak patents
- Brand and generic divide monopoly profits
- Delays agreed generic entry date beyond otherwise reasonable litigation compromise
- Consumers lose access to lower-priced generics
- FTC/ State AG enforcement priority



# The Majority View

- Second Circuit – *Tamoxifen* (2005)
- Eleventh Circuit – *Schering* (2005)
- Federal Circuit – *Ciprofloxacin* (2008)
- No violation so long as settlements are limited to **scope of patent**, absent fraud or sham litigation





## Third Circuit - *K-Dur* (2012)

- Reverse payment settlement (\$75 M) by maker of K-Dur® with two generics
- 4 year entry delay; license for other drug
- Holds reverse payment settlements presumptively unlawful
- Applies “quick look,” shifting burden to establish procompetitive justification



## Scope of the Patent Test (2d, 11<sup>th</sup>, Federal Circuits)

- Settlement's Restriction on Competition *within* the "Potential Exclusionary Scope" of a Patent is lawful.
- Settlement's Restriction is *outside* that "Potential Exclusionary Scope" if:
  1. **Fraud on the PTO**
  2. **Objectively Baseless**
  3. **Terms of Settlement Extend Beyond Patent Scope**





# Two Main Principles

- Conduct within the lawful scope of a patent is not subject to antitrust scrutiny
- Settlements are favored by our court system



# Courts Reject a Re-Examination of the Patent Merits

“We think . . . a rule, making every settlement of patent litigation . . . subject to the inevitable, *lengthy and expensive hindsight of a jury as to whether . . . the Federal Circuit would have affirmed or reversed in a patent appeal . . .* would place a huge damper on such settlements.”

*In Re: Tamoxifen Citrate Antitrust Litig.*, 429 F.3d 370, 396 n.26 (2d Cir. 2005), amended by 466 F.3d 187 (2d Cir. 2006) (internal citations omitted) (emphasis added)





# What is a "Payment"?

- Money
- License to Unrelated Product?
- Agreement not to Launch Authorized Generic?
- Distribution or Manufacturing Agreement?
- Compromise on Damages Claim or Appeal?
- Any "Value"?



# Market Definition

- What is relevant product market for assessing competitive impact of reverse payment settlement?
- Molecule market v. Therapeutic market
- Differentiated product theory
- Brands often claim and market uniqueness
- Physician prescribing practices





# Sham and Fraud Exceptions

- Do not check brand litigation incentives
- Brands lose between 50-75% of time
- Presumed immunity for litigation and patent applications
- Sham - objectively baseless standard
- *Walker Process* Fraud – common law fraud; inequitable conduct not enough

# Questions???

**Randall A. Hack**  
**Locke Lord LLP**  
**111 South Wacker Drive**  
**Chicago, IL 60606**  
**Tel: 312-443-0676**  
**Email: [rhack@lockelord.com](mailto:rhack@lockelord.com)**

**Locke**  
**Lord**  
LLP

**Charles A. Loughlin**  
**Baker Botts L.L.P.**  
**The Warner**  
**1299 Pennsylvania Ave., N.W.**  
**Washington, DC 20004**  
**Tel: 202-639-1104**  
**Email: [charles.loughlin@bakerbotts.com](mailto:charles.loughlin@bakerbotts.com)**

**BAKER BOTTS** LLP