

# **Berkeley Center for Law & Technology Advanced Patent Law Institute**

**“Pharmaceutical Reverse Payment Patent Settlements”**

Seth C. Silber

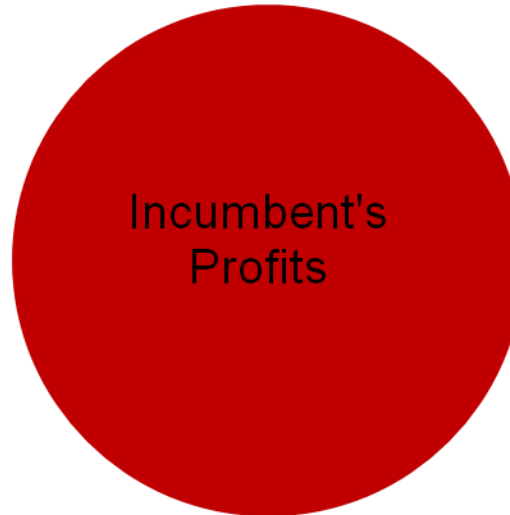
December 13, 2013

## **What Does “Pay-for-Delay” (aka “Reverse Payment”) Settlement Mean?**

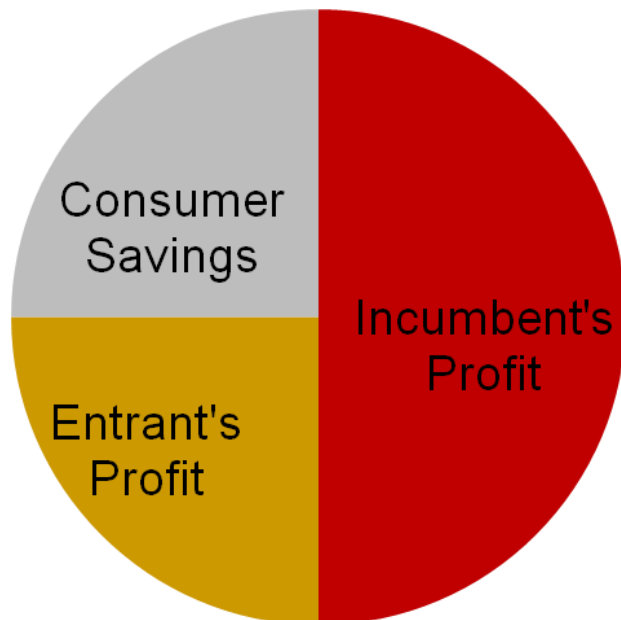
- FTC created this terminology
- Context:
  - Hatch-Waxman Act (1984)
  - Brand-Generic Paragraph IV patent settlement
- Parties settle their case whereby:
  - Generic agrees to refrain from going to market until an agreed-upon date, and
  - Brand makes “payment” to generic or provides other consideration (e.g., “side deals”, no authorized generic agreement)

# The FTC's View: Incentives to Pay to Delay Generic Entry

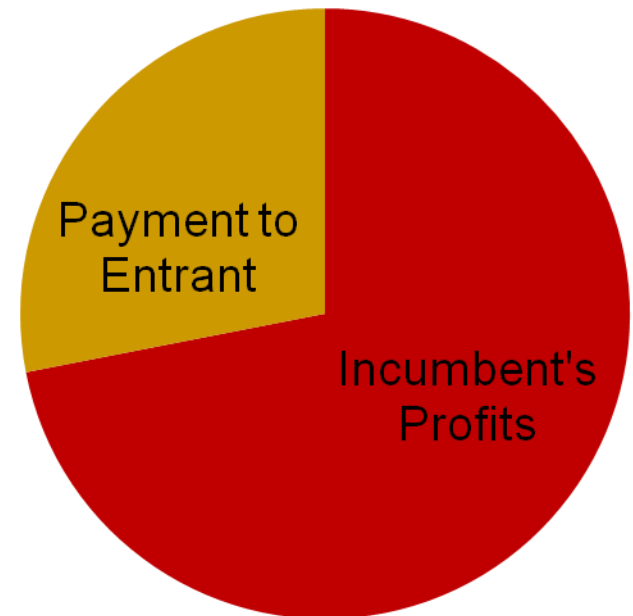
## Monopoly



## Competition



## Retained Monopoly



## FTC/Plaintiffs' Theory of Anticompetitive Harm

- Parties should be able to reach settlement with patent split based upon their objective views of the patent merits
- If compensation to generic is introduced into the settlement, the entry date (the patent split) must move to a later date in exchange for the compensation
- This delays generic entry and results in consumer harm





# The History of “Pay-For-Delay”

FTC Starts  
Investigating  
(Late 90s)

First Private Suit  
(Cardizem)  
(August 1998)

6<sup>th</sup> Cir.  
Cardizem “Per  
Se” Decision  
(June 2003)

FTC Schering  
Decision  
(Dec. 2003)

FTC v. Cephalon Filed  
(April 2008)

FTC v. Actavis Filed  
(Jan. 2009)

Private Suits Filed Re:  
Lamictal  
Lipitor  
Effexor  
Nexium  
(Dec. 2011 to Aug. 2012)

3<sup>rd</sup> Cir. K-Dur  
“Presumption of  
Illegality” Decision  
(July 2012)

Supreme Court  
Actavis Decision  
(June 2013)

11<sup>th</sup> Cir.  
Schering  
“Scope of  
Patent”  
Decision  
(March 2005)

2<sup>nd</sup> Cir.  
*Tamoxifen*  
“Scope of  
Patent”  
Decision  
(May 2005)

Fed. Cir.  
Ciprofloxacin  
“Scope of  
Patent”  
Decision  
(Oct. 2008)

1998

2003

2005

2008

2012

2013 - Future



## Edith Ramirez, Chairwoman (Democrat)

**“We look forward to moving ahead with the Actavis litigation and showing that the settlements violate antitrust law. We also are studying the Court’s decision and assessing how best to protect consumers’ interests in other pay for delay cases. Fighting anticompetitive patent settlements has been a priority for the Commission beginning under the Chairmanships of Robert Pitofsky, through Timothy J. Muris, Deborah Platt Majoras, William E. Kovacic, and culminating under the leadership of Chairman Jon Leibowitz.”**

*Statement of FTC Chairwoman Edith Ramirez on the U.S. Supreme Court’s Decision in FTC v. Actavis, Inc.*

**“The Actavis decision is an important milestone, but the commission's work is hardly over . . . Pay-for-delay settlements will not disappear.”**

*Statement of FTC Chairwoman Edith Ramirez while testifying before the Senate Judiciary Committee as part of a panel entitled “Pay-for-Delay Deals: Limiting Competition and Costing Consumers,” July 23, 2013.*

**“The Supreme Court’s decision in Actavis confirms that [reverse payment] settlements harm consumers and competition, and the Commission will continue to aggressively prosecute these anticompetitive settlements.”**

*Written testimony of FTC Chairwoman Edith Ramirez before the Senate Judiciary Committee, July 23, 2013.*

Case Name	Year of Suit	Plaintiff	Size of Market*	Size of Payment
<i>FTC v. Actavis</i>	2009	FTC/Private	\$400 M	\$100 M (approx)
<i>In re Modafinil</i>	2008	FTC/Private	\$800 M	\$200 M
<i>FTC v. Schering-Plough</i>	2001	FTC/Private	\$220 M	\$60 M
<i>In re Lamictal</i>	2012	Private	\$2 B	"No AG" agreement
<i>In re Lipitor Antitrust Litigation</i>	2011	Private	\$10.7 B	Sales Outside US and other payments
<i>In re Effexor Antitrust Litigation</i>	2011	Private	\$537 M	"No AG" agreement
<i>In Re Nexium</i>	2012	Private	\$3 B	Supply agreement and other compensation
Niaspan	2013	Private	\$1.03 B	Supply and promotion agreement
Loestrin 24	2013	Private	\$389 M	Unknown Amount

\*Annually at the time of the settlement.