



Reverse-Payments in the U.S.:

The State of Play

Markus Meier

March 10, 2016

This presentation was prepared from public sources. The views expressed herein do not necessarily reflect those of the Federal Trade Commission.

Presentation Overview

1. Explain what the FTC means by “reverse-payment” agreement.
2. Discuss the state of the law and how we got here.
3. Explain what’s at stake for consumers.
4. Look at some settlement facts and figures.
5. Highlight legal developments to watch.

Reverse-Payment Agreements

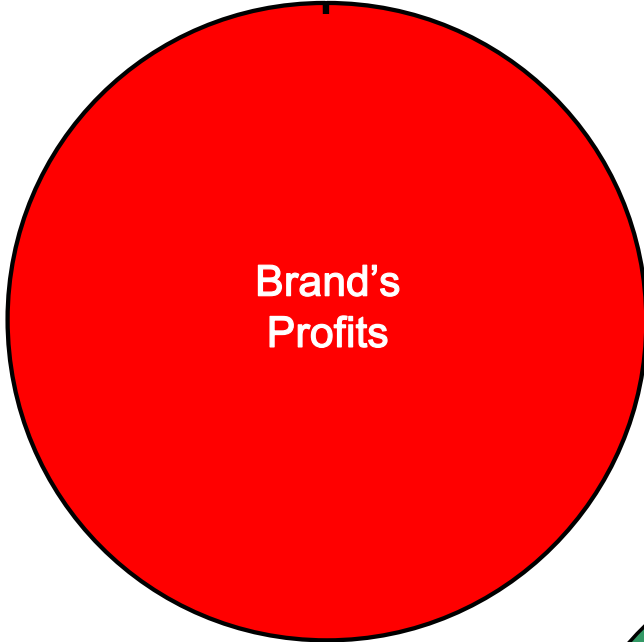
Brand and generic pharma companies enter an agreement settling patent litigation whereby:

1. Generic agrees to refrain from entering the market until a certain date.
2. Brand agrees to compensate the generic.

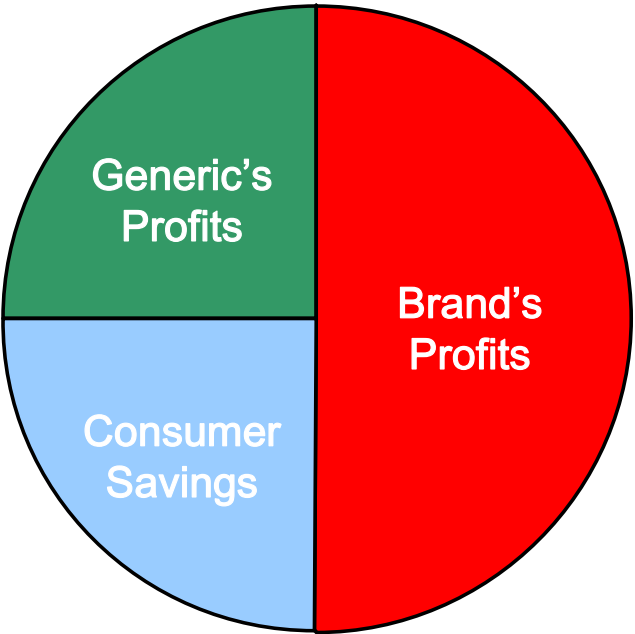
Possibly including: cash; manufacturing, API supply, co-promotion, or co-development agreements; patent licenses; or “no AG” agreements.

Incentives to Do Reverse Payments

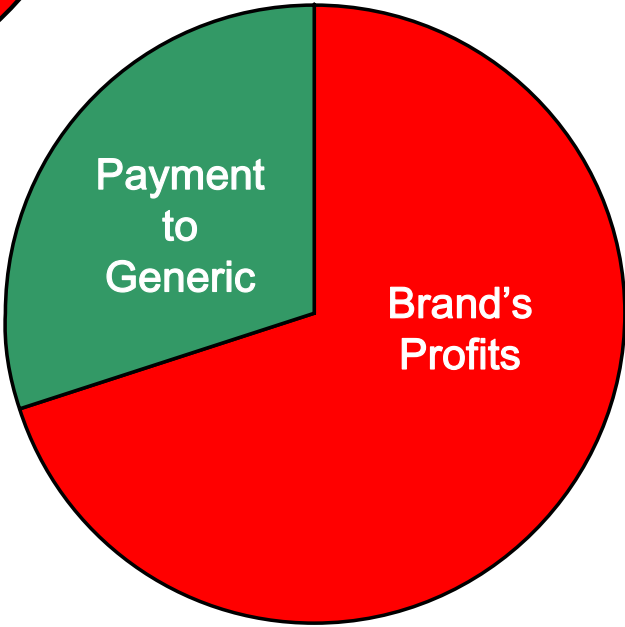
Pre-Generic Entry



Competition



Reverse Payment



Pre-Actavis Precedent

- **Circuit courts finding agreements illegal or presumptively unlawful:**
 - *In re Cardizem* (6th Cir. 2003)
 - *In re K-Dur* (3d Cir. 2012)
- **Circuit courts finding agreements legal:**
 - *FTC v. Schering-Plough* (11th Cir. 2005)
 - *In re Tamoxifen* (2d Cir. 2006)
 - *In re Ciprofloxacin* (Fed. Cir. 2008 & 2d Cir. 2010)
 - *FTC v. Watson* (11th Cir. 2012)

Approach of Courts that Found Agreements Legal

- Must consider the “scope of the patent.”
- A violation can occur only if the exclusionary effect of the agreement exceeds the potential exclusionary scope of the patent, such as:
 - If the patent was obtained by fraud
 - If the patent infringement litigation was a sham
 - If the agreement covers unrelated or obviously non-infringing products
 - If the generic agrees to stay out of the market past patent expiry

FTC v. Actavis (2013)

- Supreme Court rejects “scope-of-the-patent” test.
- Reverse-payment agreements must be analyzed under the antitrust “rule of reason.”
 - Reverse payments have the potential for “genuine adverse effects on competition.” (p. 2234)
 - “[N]ormally not necessary to litigate patent validity” to determine the competitive effects. (p. 2236)
 - “[L]eave[s] to the lower courts the structuring of the present rule-of-reason antitrust litigation.” (p. 2238)

FTC v. Actavis (continued)

- The focus of the antitrust inquiry is on **the payments, *not* the patent.**
- Key antitrust question: **Did the payment induce the generic to stay out of the market?**

“Although the parties may have reasons to prefer settlements that include reverse payments, the relevant antitrust question is: What are those reasons? If the basic reason is a desire to maintain and to share patent-generated monopoly profits, then, in the absence of some other justification, the antitrust laws are likely to forbid the arrangement.” (p. 2237)

Issues Being Contested

1. What is a “payment”?
2. What is a “large” payment?
3. Who has the burden of proof to show an “unexplained” or “unjustified” payment?
4. What can be counted as “saved litigation costs”?
5. What “justifications” are permitted?
6. What about market or monopoly power?
7. What is the role of the patent?

What's at Stake for Consumers?

- FTC staff conducted a study in January 2010 of the cost of reverse-payment agreements to consumers and payers.
- Study found that agreements with compensation restrict entry an average of 17 months longer than agreements without.
- Study estimated that reverse-payment agreements cost U.S. consumers \$3.5 billion a year.

Overview of Final Settlements (2004-2014)

Fiscal Year	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Final Settlement	14	11	28	33	66	68	113	156	140	145	160
Potential Reverse Payments	0	3	14	14	16	19	31	28	40	29	21
Potential Reverse Payments with First Filers	0	2	9	11	13	15	26	18	23	13	11

What's Next for the FTC?

- Pursue reverse-payment cases currently in litigation.
 - *FTC v. Actavis* (2009) and *FTC v. Abbvie* (2014)
- Monitor private litigations and file amicus briefs as appropriate.
 - *Effexor XR, Wellbutrin, Lamictal* (3d Cir.), *Loestrin* (1st Cir.), *Nexium* (1st Cir.)
- Investigate new reverse-payment matters.
- Re-examine agreements filed under the Medicare Modernization Act (MMA) of 2003.

20 Cases to Watch

- **The cases** (by brand name)

Adderall, Aggrenox, AndroGel (2x), Cipro, Effexor, Epi-Pen, K-Dur, Lamictal, Lidoderm, Lipitor, Loestrin, Nexium (2x), Niaspan, Opana, Provigil, Skelaxin, Solodyn, Wellbutrin

- **The brand companies**

Abbvie, Abbott, AstraZeneca, Bayer, Besins, Biovail, Boehringer, Cephalon, Endo, GlaxoSmithKline, King, Medicis, Pfizer, Shire, Schering, Warner Chilcott, Wyeth

- **The generic companies**

Actavis , AHP, Barr, Duramed, Dr. Reddy's, HMR, Impax, Lupin, Mutual, Mylan, Par, Perrigo, Ranbaxy, Rugby, Sandoz, Teva, Upsher Smith

www.ftc.gov