



FTC Briefing on Pharmaceutical Reverse-Payment Agreements

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Session Overview

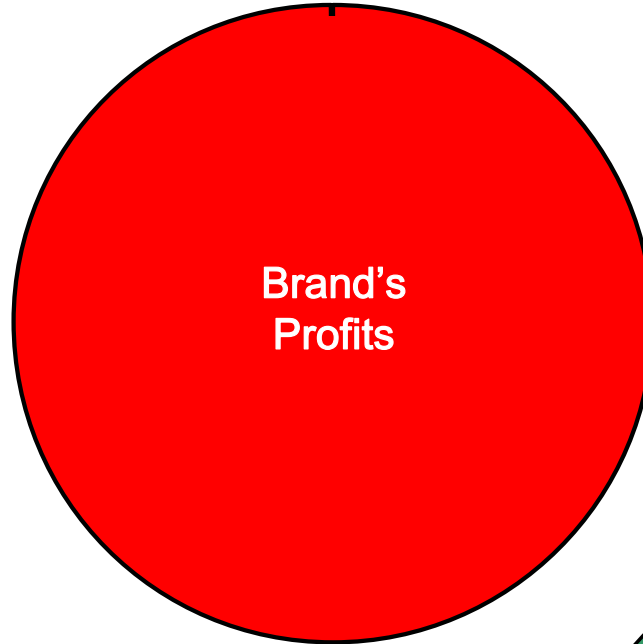
1. Explain what the FTC means by “reverse-payment agreement.”
2. Discuss the current state of the law and how we got here.
3. Explain what’s at stake for consumers.
4. Highlight some developments to watch.
5. Take questions.

Reverse-Payment

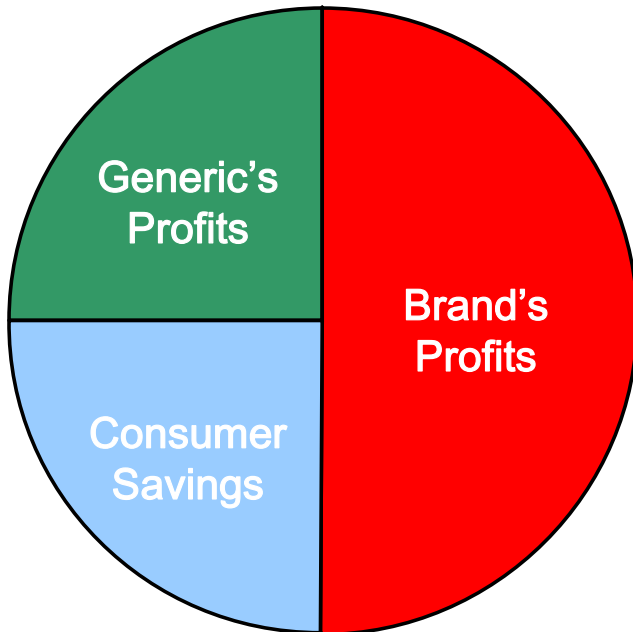
- Brand and generic in patent litigation settle the case.
 1. Generic agrees to refrain from going to market until a certain date.
 2. Agreement includes compensation from the brand to the generic (“reverse payment”):
 - possibly including cash; IP licenses; co-promotion, co-development, manufacturing, API supply, or “no AG” agreements.

Incentives to Pay for Delay

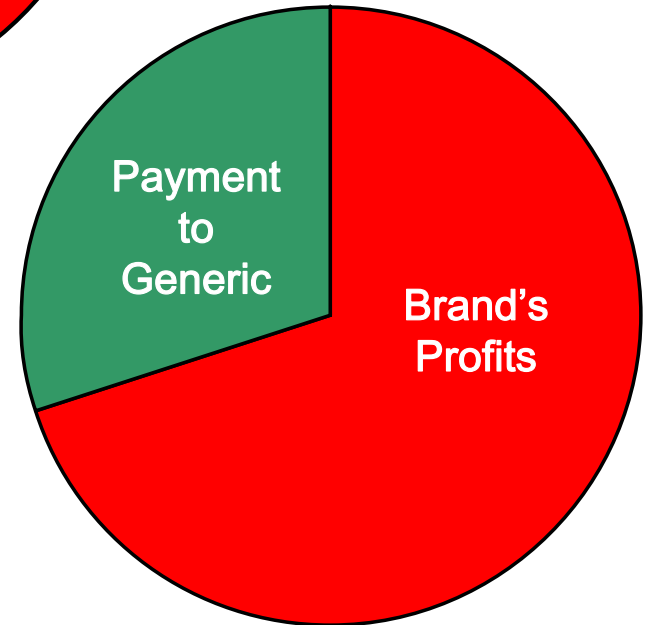
Pre-Generic Filing



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 Settlements 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

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

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 Likely to Be 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 & what proof is required?
4. What can be counted as “saved litigation costs”?
5. What “other justifications” are permitted?
6. What about market or monopoly power?
7. What is the role of the patent?

What's at Stake for Consumers?

If reverse-payment agreements are permitted, consumers and payers will lose the benefits of generic entry prior to patent expiration arising from:

1. Generic victories in patent litigation.
2. Settlements without reverse payments.
3. “At risk” entry by generics.

FTC Staff Study

- 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.

FTC Review of Patent Settlements

(2004-2012)

Fiscal Year	2004	2005	2006	2007	2008	2009	2010	2011	2012
Final Settlements	14	11	28	33	66	68	113	156	140
Potential Reverse Payments	0	3	14	14	16	19	31	28	40
	0%	27%	50%	42%	24%	28%	27%	18%	29%
Final Settlements Involving First Filers	8	5	11	16	29	32	49	54	43
Potential Reverse Payments Involving First Filers	0	2	9	11	13	15	26	18	23
	0%	40%	82%	69%	45%	47%	53%	33%	53%

What's Next for the FTC?

- Pursue matters currently in litigation.
 - *FTC v. Actavis* , *FTC v. Cephalon*, & *FTC v. Abbvie*
- Monitor private litigations and file amicus briefs as appropriate.
 - *Effexor XR* (D. N.J.), *Wellbutrin* (E.D. Pa.), & *Lamictal* (3d Cir.)
- Investigate new matters.
- Re-examine settlements filed under the Medicare Modernization Act (MMA) of 2003.

19 Cases to Watch

- **The cases** (by name of the brand product)

Actos, Adderall, Aggrenox, **AndroGel**, Cipro, Effexor, K-Dur, **Lamictal**, Lidoderm, **Lipitor**, **Loestrin**, **Nexium**, Niaspan, Opana, **Provigil**, Skelaxin, Solodyn, Wellbutrin

- **The brand companies**

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

- **The generic companies**

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

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