

Pharmaceutical Patent Settlements: Illegal “Pay-for-Delay” or Lawful Resolution of Complex Disputes?

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Overview

1. Explain what a “pay-for-delay” settlement is and make the case for why these settlements violate the antitrust laws.
2. Explain how pharmaceutical companies try to resolve complex patent disputes and make the case for why these settlements are lawful.
3. Respond to the arguments for and against the legality of the settlements.
4. Highlight some important developments to watch.
5. Take questions.

Pay-for-Delay Settlements

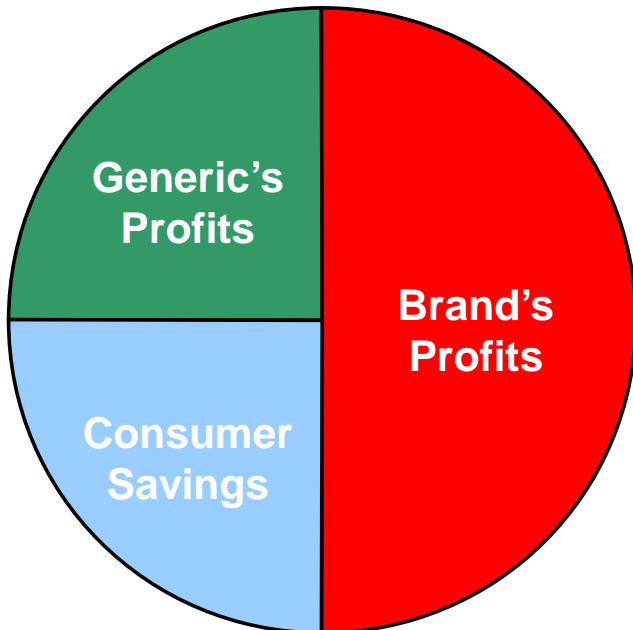
- Brand and generic in patent litigation settle the case.
- Generic agrees to refrain from entering market until a certain date.
- Settlement includes payment or other consideration from the brand to the generic
 - possibly including cash; IP licenses; co-promotion, co-development, manufacturing, API supply, or “no authorized generic” agreements

Incentives to Pay for Delay

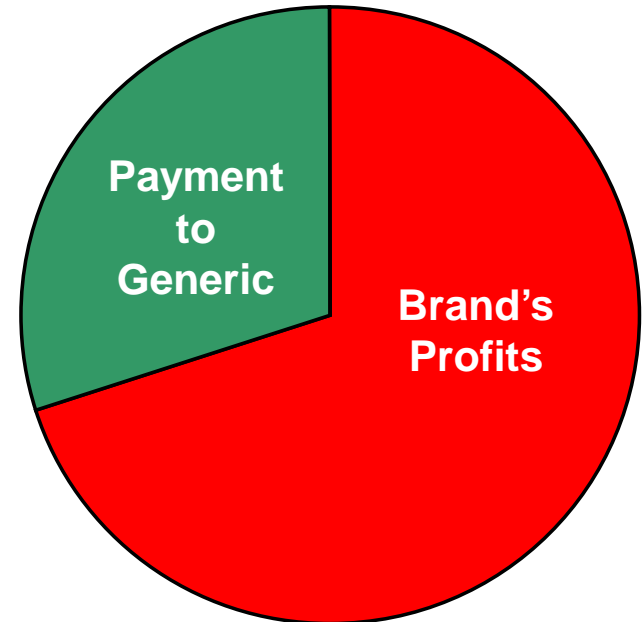
Pre-Generic Filing

an
of

Competition



Exclusion Payment



Theories of Antitrust Violation in Pay-for-Delay Cases

- Unfair method of competition – FTC Act § 5
- *Per se* illegal market division – Sherman Act § 1
- Agreement in restraint of trade – Sherman Act § 1
- Monopolization, attempted monopolization, and conspiracy to monopolize – Sherman Act § 2

FTC's Pay-for-Delay Cases

- *Abbott/Geneva* (Hytrin/terazosin) – consent order (2000)
- *Hoechst/Andrx* (Cardizem) – administrative litigation & consent order (2001)
- *American Home Products* (K-Dur) – administrative litigation & consent order (2002)
- *Bristol-Myers Squibb* (BuSpar) – consent order (2003)
- *Schering/Upsher-Smith* (K-Dur) – administrative litigation, 11th Circuit appeal, Supreme Court denied cert (2006)
- *FTC v. Cephalon* (Provigil) – case in E.D. Pa. (2008)
- *FTC v. Watson* (AndroGel) – case filed in N.D. Ga. (2009), judge dismissed (2010), will be appealed to 11th Circuit

State of the Law in U.S.

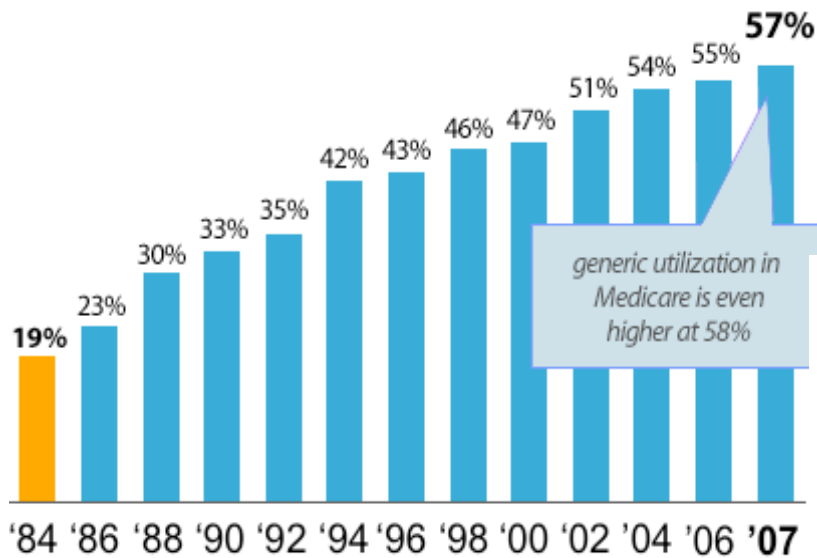
- Circuit Court finding settlement illegal:
 - *In re Cardizem* (6th Cir., 2003)
- Circuit Courts upholding settlements as legal:
 - *FTC v. Schering-Plough* (11th Cir., 2005)
 - *In re Tamoxifen* (2d Cir., 2006)
 - *In re Ciprofloxacin* (Fed. Cir., 2008 & 2d Cir 2010)

Approach of Courts Finding 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.
- The exclusionary effect of the agreement exceeds the exclusionary scope of the patent:
 - If the patent was obtained by fraud
 - If the patent infringement litigation was a sham
 - If the agreement covers unrelated or obviously noninfringing products

The Current US System Is Working

The Generic's Share of Prescription
Unit Volume US, 1984-2007



Savings Generated By Use of Generic Drugs During
First Decade of Hatch-Waxman Act, 1999-2008
\$billions



Source: Economic Analysis of Generic Pharmaceuticals 1999-2008, \$734 Billion in Health Care Savings, Generic Pharmaceutical Association, May 2009

Why Do Companies Settle?

- Assume:
 - Big Pill has a patent on K-Pow, a prescription drug, which expires in 2015.
 - K-Pow has annual sales of \$1 billion.
 - Big Pill invested tens of millions of dollars and many years in developing and marketing K-Pow.
 - K-Pow has some unique properties (e.g., fewer side effects) but is similar to other products on the market.
 - There is a Paragraph IV ANDA first filer, Cheap Pill Co.

Why Do Companies Settle?

- Under U.S. law, a Paragraph IV ANDA first filer is the first to contend the patent is invalid or not infringed, starting a litigation process.
- First filer is not allowed to enter for 30 months. If the first filer enters thereafter, it gets 6 months of exclusivity as the only FDA-approved generic.
- Generics take most sales away from the brand name drug within the first six months of entry.

Why Do Companies Settle?

- So...
 - Big Pill sues Cheap Pill, claiming patent infringement.
 - Cheap Pill claims the Big Pill's patent is invalid and that its generic does not infringe the patent.
 - Big Pill denies; thinks it has strong patent case.
 - In preliminary discussions with court, the judge doesn't seem to think Big Pill's patent defense is all that strong, but there have been no rulings yet. Case could go either way.
 - Big Pill has some concern Cheap Pill might enter "at risk" – i.e., launch before the courts have resolved the patent litigation.

Why Do Companies Settle?

- IP Litigation will cost Big Pill \$5 - \$10 million . . .
- Cheap Pill will settle, and will stipulate the patent is valid, in exchange for:
 - Licensed early entry in June 2013
 - Exclusive license to Cheap Pill for the first six months
 - A marketing agreement where Cheap Pill promotes K-Pow for an annual fee, plus “per-detail” fees
 - \$5 million to cover litigation costs
- They agree. What’s wrong with that?

The Industry Contends

- The agreement lawfully settles disputed litigation. Big Pill can license as it sees fit within the bounds of the patent.
- The settlement is pro-competitive because it allows entry 2 years before patent expires. There was no pay for delay because:
 - Cheap Pill was not going to enter at risk. The damages risk, based on branded product lost profits, was too great.
 - Cheap Pill's IP case might have failed.
- K-Pow competes with other products and lacks market power.
- The co-promotion agreement was at fair market value and is “output expanding.” Cheap Pill has a well-trained sales force that will enhance K-Pow's sales.
- Cheap Pill will use the money it would have spent litigating the case and the \$5 million in settlement and has invested in other generic challenges.

The Industry Contends

- Patents Matter
 - A settlement is lawful if it **(1)** does not “extend the monopoly beyond the patent’s scope,” **(2)** the patent was not procured by fraud, and **(3)** the infringement suit was not “objectively baseless in the sense that no reasonable litigant could realistically expect success ...” *Tamoxifen*, 466 F.3rd 187, 213 (2nd Cir. 2006)
 - “A settlement is not unlawful if it serves to protect that to which the patent holder is legally entitled – a monopoly over the manufacture and distribution of the patented invention.” *In re Ciprofloxacin Hydrochloride Antitrust Litig.*, 54 F.3d 1323 (Fed. Cir. 2008).
- Contrary rule would throw many licensing deals into question.
- Settlements Encourage Patent Challenges
 - FTC rule means fewer patent challenges and more generic losses.
 - Not always clear early entry alone will secure a settlement.
 - Generic firms take value and invest in other patent challenges.¹⁵

Defendants Raise Patent Law as a Defense in Pay-for-Delay Cases

- Argue that patents are “presumed” valid
- Assert they are merely exercising their rights under the patent laws to exclude infringers
- But the “scope of the patent” does not include the right to use monopoly profits to pay off potential competitors

Balancing Patent & Antitrust Law

- *“The presumption [of patent validity] is one of law, not of fact, and does not constitute ‘evidence’ . . . It simply places the burden of persuasion on the party challenging validity.”* Robert L. Harmon, *Patents in the Federal Circuit* 27 (4th ed. 1998).
- The Patent Act and case law establish two methods a patent holder may try to use to exercise its right to exclude:
 - Refuse to license and persuade accused infringer to unilaterally accede to the patent
 - Seek an injunction from a court
 - For permanent injunction – must prove infringement and ward off challenge to validity
 - For preliminary injunction – must show likelihood of success on merits
 - Alleged infringer has right to compete absent showing of infringement

“Settlements Permit Early Generic Entry!” . . . But Do They *Really*?

- Here’s what Cephalon’s lawyers told the Court in Cephalon’s May 2008 motion to dismiss:

“The Settlements permitted the Generics to enter the market three years prior to expiration of the ‘516 patent . . . [which has] obvious benefits and efficiencies” (memorandum at p. 1)

- But here’s what Cephalon’s CEO told investors in a February 2009 earnings call about its planned switch from Provigil to Nuvigil:

“We have to remember if we do our job right . . . the PROVIGIL number in 2012 that will be genericized will be very, very small.” (transcript at p. 9)

Brand/Generic Settlements Over Time

	No Antitrust Actions	Antitrust Actions Initiated	<i>Schering and Tamoxifen</i> Decisions	Post- <i>Schering and Tamoxifen</i>	Post- <i>Schering and Tamoxifen</i>
	1992 to 1999	2000 to 2004*	2005	2006	2007
Final Settlements	14	20	11	28	33
Payments and Entry Restrictions	9	0	3	14	14

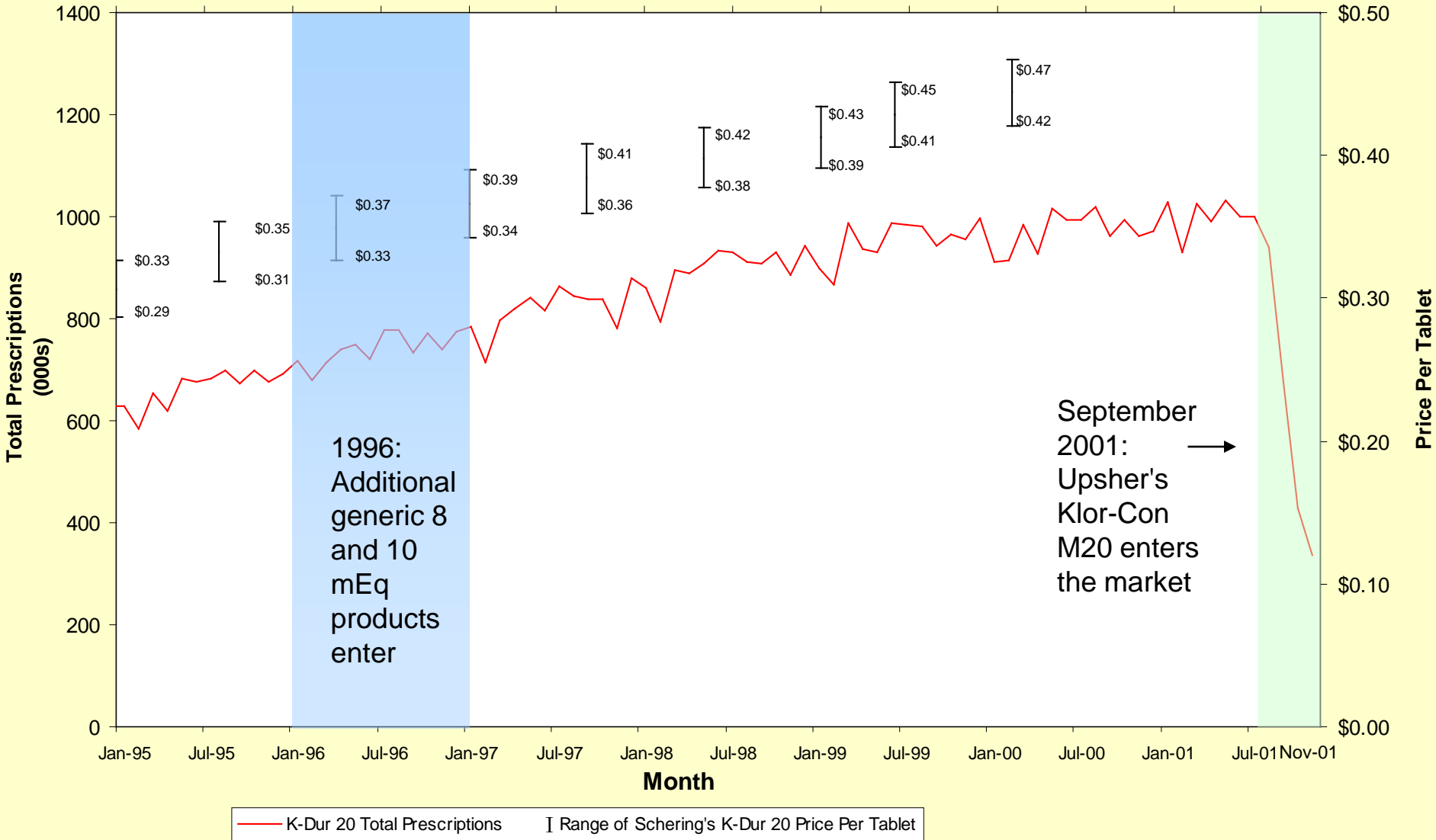
*The Commission does not have data for 2003

Forms of Compensation in Brand/Generic Settlements Over Time

	No Antitrust Actions	Antitrust Actions Initiated	<i>Schering</i> and <i>Tamoxifen</i> Decisions	Post- <i>Schering</i> and <i>Tamoxifen</i>	Post- <i>Schering</i> and <i>Tamoxifen</i>
	1992 -1999	2000 - 2004*	2005	2006	2007
Settlements w/ comp. and deferred entry	9	0	3	14	14
Cash	7	0	0	1	0
Side Deals	2	0	2	10	3
No Authorized Generic	0	0	1	3	11

*The Commission does not have data for 2003.

Only Generic K-Dur 20 Constrains Sales of K-Dur 20 (Generic 8 and 10 mEq Had No Effect on K-Dur 20 Sales)



Sources: Total Prescriptions- CXs 81-82 (1995-1996), 62-65 (1997-2000), 1480 (2001); Pricing- CX 49

* See USX 626 at USL15228; IDF 406

Some Developments to Watch

- *Cipro* en banc appeal to Second Circuit
- *FTC v. Watson* appeal to Eleventh Circuit & private actions (N.D. Ga.)
- *FTC v. Cephalon* & private actions (E.D. Pa.)
- Legislation & the Obama Administration

Cipro Appeal

- Second Circuit panel issued its decision on 4/29/10 – follows *Tamoxifen* and upholds decision in favor of defendants
- But Second Circuit may be re-thinking its *Tamoxifen* decision
 - “because of the ‘exceptional importance’ of the antitrust implications,” the court invites plaintiffs to petition for a rehearing en banc

AndroGel Cases

- Judge Thrash in N.D. Ga. granted in part and denied in part defendants' motions to dismiss on 2/22/10
- Plaintiffs' sham litigation claims survive & case is proceeding
- FTC case dismissed, but plans to appeal to Eleventh Circuit
 - What is the Eleventh Circuit's "scope of the patent" test?

Cephalon (Provigil) Cases

- Judge Goldberg in E.D. Pa. denied defendants' motions to dismiss on 3/29/10
- Plaintiffs include FTC, direct purchasers, end payers, and Apotex
- Discovery schedule issued on 4/27/10
- What is Judge Goldberg's "scope of the patent" test going to be in practice?

Judge Goldberg's "Scope of the Patent" Test (at p. 30)

“ . . . the complaints allege [1] fraud and misrepresentations to the PTO, [2] non-infringement, [3] patent invalidity, [4] ‘sham litigation’, [5] the creation of a bottleneck, [6] antitrust conspiracy and [7] agreements between Cephalon and the Generic Defendants regarding products not protected by Cephalon’s patent.”

“To the extent that a factual basis exists on any of these theories, Plaintiffs may be able to prevail under the scope of the patent test and move forward with their antitrust claims.”

Legislation

- Legislation restricting pay-for-delay almost included in recent health-care reform bill
 - Bright-line ban included in House's health-care bill
 - Senate Judiciary Committee, with bi-partisan support, reported a bill making practice presumptively illegal
 - President included provision similar to Senate bill in his health-care reform bill
- Senator Kohl has announced intention to re-introduce his bill
- CBO in 1/28/10 report "scored" S.369 as saving federal government billions of dollars

Questions?