DRUG PATENT SETTLEMENTS AND THE UNEASY CASE FOR CENTRALIZATION

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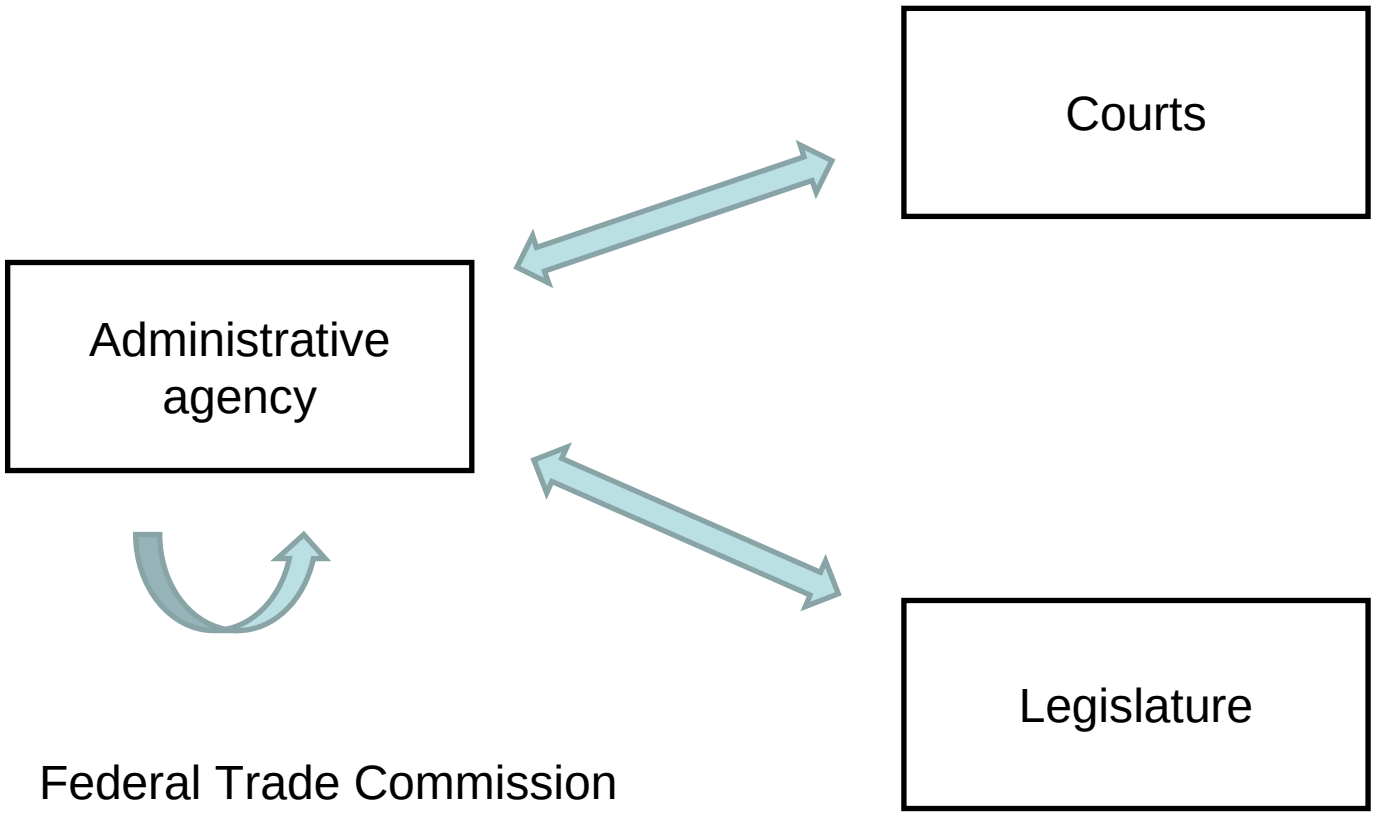
June 15, 2007

TODAY: THREE INTERACTIONS



- Federal Trade Commission
- Antitrust Division of Department of Justice

TODAY: THREE IMPLICATIONS OF CENTRALIZATION

Consistency: Agency Versus Agency

Expertise: Court Versus Agency

Specificity: Industry-Specific Antitrust?

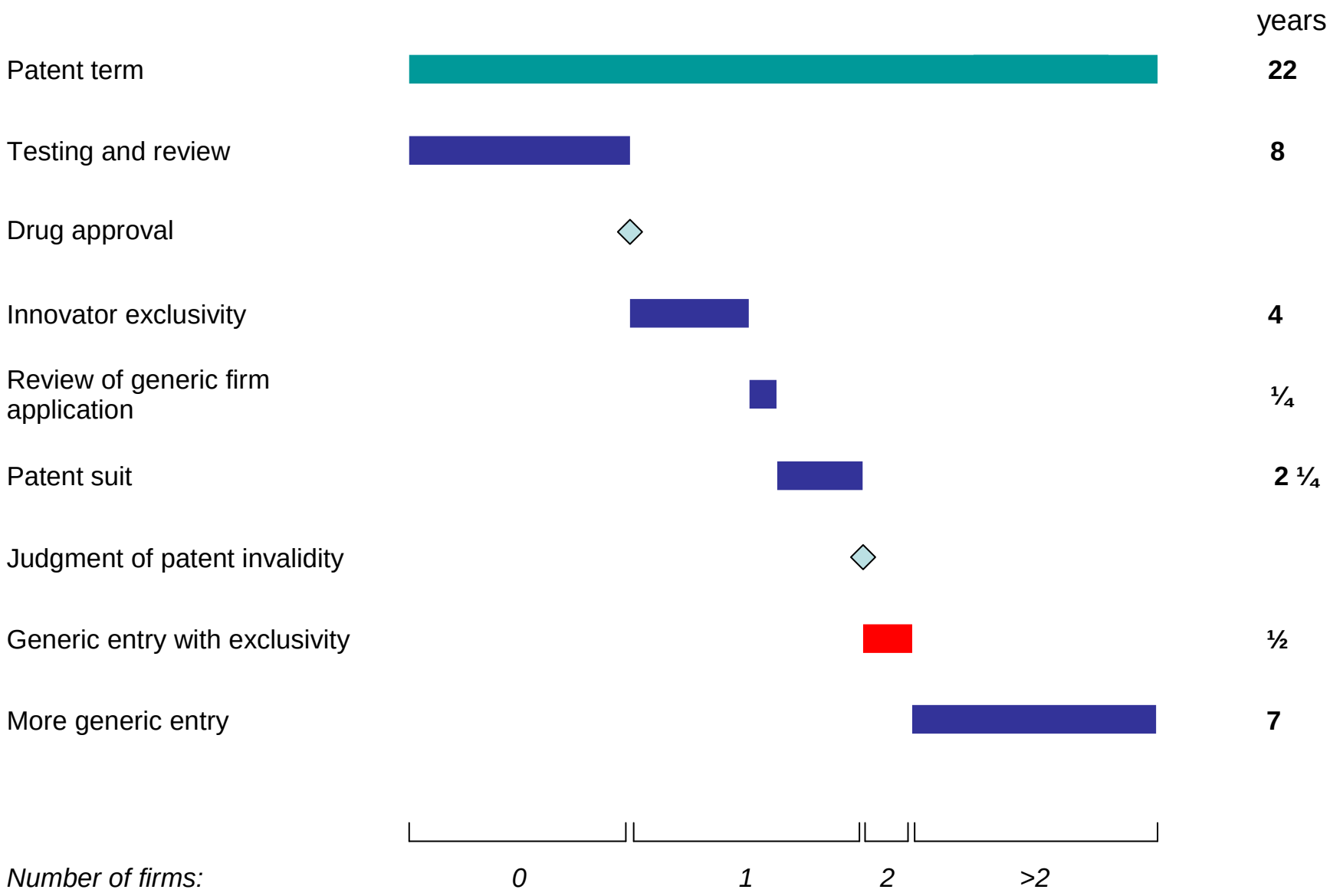
U.S. DRUG MAKER INCENTIVES ARE SHAPED BY AN ATYPICAL INNOVATION TECHNOLOGY AND UNIQUE REGULATORY REGIME

An unusually “simple” innovation path

Different patent term length

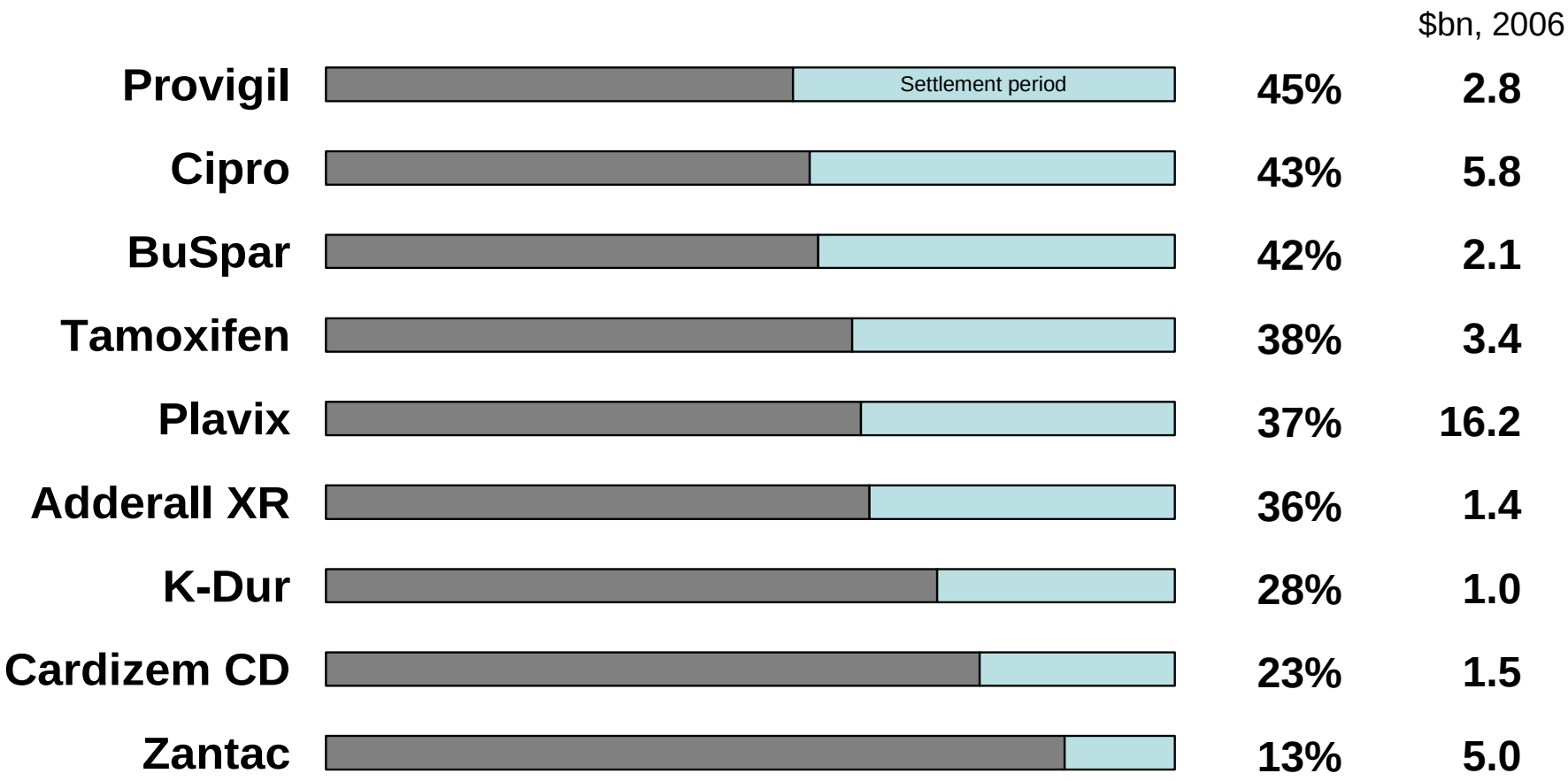
Industry-specific regulation

THE REGULATORY STRUCTURE CREATES AN OPPORTUNITY TO COLLUDE



SETTLEMENT IS A MAJOR COMPONENT OF LIFECYCLE MANAGEMENT

Fraction of exclusivity period covered by settlement with a rival



Settlement period assumed to end at date of agreed-upon entry; dollar value revenue growth matching inflation during settlement period; Plavix agreement never implemented; Adderall XR sales estimated as 60 percent of global sales

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THE FTC AND ANTITRUST DIVISION HAVE TAKEN DIVERGENT VIEWS

At the Supreme Court

- *Schering*
  - FTC requested certiorari
  - Justice Department filed brief against certiorari
- *Tamoxifen*
  - FTC supports certiorari (unofficially)
  - Justice Department filed brief against certiorari
  - Justices may decide on June 21

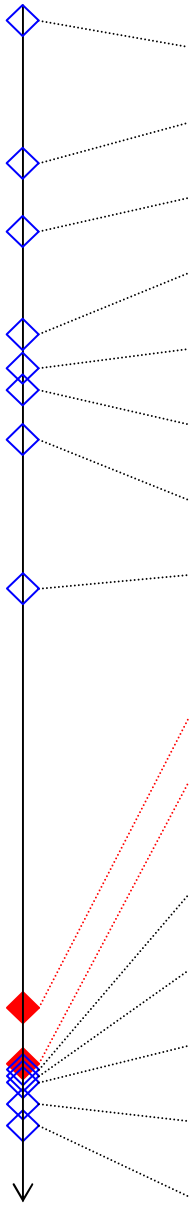
Enforcement actions

- FTC investigations include Provigil, Actiq, Plavix, and Adderall XR
- Justice Department remains skeptical; did participate in Plavix criminal inquiry

In Congress

- FTC has urged legislative action repeatedly
- Antitrust Division has remained silent

DIVERGENT POSITIONS HAVE ENCOURAGED A SECOND SETTLEMENT WAVE



		Agency	Court	Notes
1993	Tamoxifen		✓	CA2; cert. pending
1994	BuSpar	✓		Consent decree
1995	Zantac			
1997	Cipro		✓	EDNY; CA2 pending
1997	K-Dur	✓	✓	CA11
1997	Cardizem CD	✓	✓	CA6
1998	Hytrin	✓	✓	CA11 remand
2000	Procardia XL		✓	$9 million settlement
3/05	*Schering* (K-Dur), CA11			
11/05	*Tamoxifen*, CA2			
12/05	Effexor XR			
1/06	Provigil	✓		FTC inquiry
2/06	Provigil/Actiq	✓		FTC inquiry
5/06	Plavix	✓		DOJ and FTC probes
8/06	Adderall XR	✓		FTC inquiry

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PAYMENT AND DELAY TAKE MULTIPLE FORMS

Payment to generic firm

- Cash
- Mispriced transfers
  - Overpayment for side deals
  - Undercompensation for private label sales
- Preservation of generic exclusivity
  - Declining to challenge
  - Declining to launch authorized generic

Delay in generic entry

- Neutralizing first filer
- Bottleneck
- Interim delay
- Noninfringing products

SECOND-WAVE SETTLEMENTS ARE ANTICOMPETITIVE, BUT IN WAYS LESS APPARENT TO COURTS

	First wave	Second wave
Scope	Noninfringing products	This product only
Entry date	After expiration	Before expiration
Overpayment and undercompensation	No	Yes

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MOVING FROM A STANDARD TO A RULE

Proposals

- Senate: amend the Clayton Act (new §28) to prohibit agreements that combine payment and delay
- House: amend the FTC Act §5 to prohibit agreements that combine payment and delay; rulemaking to identify exceptions where warranted

But…

- Can legislation keep pace with continuous changes in industry practice?
- How effective are measures that apply only prospectively?
- Does specificity undermine a functional approach to antitrust?

Table 1. Summary of innovator-generic drug patent settlements

Drug	US Sales	Parties	Agreement		Antitrust activity
Procardia *Nifedipine*	$364 m	Pfizer-Chase	__. 1990	? – Entry with exclusivity	None
Nolvadex *Tamoxifen citrate*	$265 m	Zeneca-Barr	Mar. 1993	$ $66 million $ Private label sales $ Possibility of 180 days Δ Neutralize first filer Δ Possibility of bottleneck Δ Vacate adverse ruling Δ Entry in Aug. 2002	Consumer/third party payor suit Pending petition for certiorari Below: CA2, NO
BuSpar *Buspirone HCl*	$288 m	Bristol-Schein	Dec. 1994	$ $73 million Δ Neutralize first filer Δ Bottleneck Δ Entry in Nov. 2000	FTC consent decree MDL suit Dismissed in part as out of time (SDNY) Settlement
Zantac *Ranitidine*	$2150 m	Glaxo-Genpharm	Oct. 1995	$ $133 million $ 180 days $ Licenses outside U.S. Δ Neutralize first filer Δ Entry in Aug. 1997	None
Cipro *Ciprofloxacin*	$680 m	Bayer-Barr	Jan. 1997	$ $398 million $ Private label sales (6 mos.) $ Possibility of 180 days Δ Neutralize first filer Δ Possibility of bottleneck Δ Entry in Dec. 2003	MDL purchaser suit Pending in CA2 Below: EDNY, NO State court suits in California, Florida, Kansas, New York, and Wisconsin All pending

Drug	US Sales	Parties	Agreement		Antitrust activity
K-Dur *Potassium chloride extended release*	$190 m	Schering-Upsher	June 1997	$ $60 million $ 180 days Δ Neutralize first filer Δ Bottleneck Δ Entry in Sept. 2001 Δ Licenses to G's products Δ Other products excluded	FTC consent decree (as to ESI) FTC suit (as to Upsher) CA11, NO MDL purchaser suit Pending in DNJ (after denying dismissal)
		Schering-ESI (L)	Jan. 1998	$ $30 million Δ Entry in Jan. 2004 Δ Licenses to G's products Δ Other products excluded	
Cardizem CD *Diltiazem HCl controlled release*	$692 m	HMR-Andrx	Sept. 1997	$ $90 million Δ Bottleneck Δ No launch at risk Δ Other products excluded	FTC consent decree Competitor suit Settled after CADC denied dismissal
		HMR-Purepac (L)	May 1999	? – Entry following expiration of exclusivity period	Purchaser suit $110 m settlement with direct purchasers $80 m settlement with indirect purchasers, states CA6, YES, as to nonsettling parties
Hytrin *Terazosin HCl*	$542 m	Abbott-Geneva	Apr. 1998	$ $101 million Δ Bottleneck Δ No launch at risk Δ Other products excluded	FTC consent decree MDL suit Pending in S.D. Fla. after SJ for plaintiffs Prior: Remand from CA11 in *Valley Drug* Kaiser Foundation Health Plan suit Pending in CA9 Below: C.D. Cal, NO
		Abbott-Zenith (L)	Mar. 1998	$ $45 million Δ Entry in February 2000 Δ Other products excluded	
Prozac *Fluoxetine HCl*	$2090 m	Lilly-Barr Lilly-Geneva	Mar. 1999	$ $4 million Quick appeal to CAFC Dismissal of two claims Δ No launch at risk	None

Drug	US Sales	Parties	Agreement		Antitrust activity
Naprelan *Naproxen sodium*	$59 m	Elan-SkyePharma	May 1999	$ License $ 180 days Δ Neutralize first filer Δ Bottleneck	Competitor suit Pending in S.D. Fla. on remand Prior: CA11, YES, denying dismissal Purchaser suit Pending in E.D. Pa., stayed for competitor suit
Procardia XL *Nifedipine extended release*	$311 m	Pfizer-Mylan Pfizer-Andrx (L)	Feb. 2000 Mar. 2001	$ Private label sales $ Possibility of 180 days Δ Neutralize first filer Δ Possibility of bottleneck ? – Protocol for determining infringement, plus licensing	Competitor suit $9 m settlement after dismissal denied Purchaser suits Settled after class status denied, N.D. W. Va.
Wellbutrin SR *Bupropion HCl sustained release*	$1600 m	Glaxo-Watson (L) Glaxo-Eon (L)	July 2001 Apr. 2004	$ Private label sales Δ Neutralize filer $ $3 million Abandonment of I's suit	
Zoloft *Setraline HCl*	$2582 m	Pfizer-Ivax	June 2002	$ 180 days Δ Neutralize first filer Δ Bottleneck Δ Entry in June 2006	None
Paxil *Paroxetine HCl*	$1933 m	Glaxo-Par (L) Glaxo-Synthon (L)	Apr. 2003 Dec. 2003	$ Profits as AG Δ Neutralize filer [Royalty-bearing agreement]	Competitor suit Dismissed
Zyprexa *Olanzapine*	$3000 m	Lilly-Ivax Lilly-Dr. Reddy's	Aug. 2003	Dismissal of claim Dismissal of defenses	None
Glucotrol XL *Glipizide extended release*	$297 m	Pfizer-Alza	Sept. 2003	$ 180 days Δ Neutralize first filer Δ Bottleneck Δ Entry in January 2004	None

Drug	US Sales	Parties	Agreement		Antitrust activity
Ovcon 35 *Norethindrone and ethinyl estradiol*	$72 m	Warner Chilcott-Barr	Mar. 2004	$ $20 million Δ Entry in May 2009 Δ Manufacturing	FTC suit Settled as to Warner Chilcott Pending in D.D.C. after denial of dismissal State attorneys general suits Pending Private plaintiffs suits Pending
Estrostep *Norethindrone and ethinyl estradiol*	$42 m	Warner Chilcott-Barr	Apr. 2004	$ Product license Δ Neutralize first filer Δ Bottleneck Δ Entry in October 2007	FTC investigation, resolved
FemHRT *Norethindrone and ethinyl estradiol*	$61 m	Warner Chilcott-Barr	Apr. 2004	$ Product license Δ Neutralize first filer Δ Bottleneck Δ Entry in November 2009	FTC investigation, resolved
Paraplatin *Carboplatin aqueous solution*	$537 m	Bristol-Teva	Apr. 2004	$ Private label sales Δ Neutralize first filer Δ Entry in October 2004	FTC clearance
Lamictal *Lamotrigine*	$1034 m	Glaxo-Teva	Feb. 2005	$ Product license $ 180 days Δ Neutralize first filer Δ Bottleneck Δ Entry in Mar. 2008	None
Niaspan *Niacin extended release*	$380 m	Kos-Barr	Apr. 2005	$ Cash $ 180 days Δ Neutralize first filer Δ Bottleneck Δ Entry in Sept. 2013 S Promotion S Manufacturing	None
Mircette *Desogestrel and ethinyl estradiol*	?	Organon-Barr	Dec. 2005	Merger	FTC merger investigation, resolved
Effexor XR *Venlafaxine HCl extended release*	$2275 m	Wyeth-Teva	Dec. 2005	$ New product line $ 180 days Δ Neutralize first filer Δ Bottleneck Δ Entry in July 2010	None

Drug	US Sales	Parties	Agreement		Antitrust activity
Provigil *Modafinil*	$476 m	Cephalon-Teva	Dec. 2005	$ Part of $219 million $ 180 days Δ Neutralize first filer Δ Bottleneck Δ Entry in October 2011 S Intellectual property S Manufacturing and supply	FTC investigation Purchaser suit Pending in E.D. Pa. Competitor suit Pending in E.D. Pa.
		Cephalon-Ranbaxy	Dec. 2005	$ Part of $219 million $ 180 days Δ Neutralize first filer Δ Bottleneck Δ Entry in October 2011 S Intellectual property S Supply	
		Cephalon-Mylan	Jan. 2006	$ Cash $ 180 days Δ Neutralize first filer Δ Bottleneck Δ Entry in October 2011 S Product development	
		Cephalon-Barr	Feb. 2006	$ Part of $219 million $ 180 days $ Actiq-specific terms Δ Neutralize first filer Δ Bottleneck Δ Entry in October 2011 S Intellectual property S Inventory	
		Cephalon-Carlsbad (L)	Aug. 2006	Δ Entry in Apr. 2012	
Actiq *Oral transmucosal fentanyl citrate*	$395 m	Cephalon-Barr	Feb. 2006	$ Earlier license $ Share of sales in another product?	FTC investigation

Drug	US Sales	Parties	Agreement		Antitrust activity
Alphagan *Brimonidine tartrate 0.15% ophthalmic solution*	$200 m	Allergan-Alcon	Mar. 2006	$ Dismiss second suit Δ Entry in September 2009	None
Altace	?	King-Cobalt	Apr. 2006		FTC investigation
Plavix *Clopidogrel bisulfate*	$3200 m	Bristol-Apotex	May 2006	$ $40 million $ 180 days $ Launch-at-risk protection $ No authorized generic* $ Breakup fee* Δ Neutralize first filer Δ Bottleneck Δ Entry in Apr. 2011 S Inventory **Disputed in part* *Not fully implemented*	Department of Justice criminal inquiry FTC investigation Purchaser suit Pending in S.D. Ohio
Biaxin XL *Clarithromycin extended release*	$151 m	Abbott-Teva Abbott-Ranbaxy (L)	July 2006 July 2006	Unknown Unknown	None
Adderall XR *Mixed amphetamine salts, extended release*	$864 m	Shire-Barr Shire-Impax (L)	Aug. 2006 Jan. 2006	$ $102 million $ 180 days $ No authorized generic $ New product line Δ Neutralize first filer Δ Bottleneck Δ Apr. 2009 entry S Develop/supply other products $ Cash Δ Entry in Jan. 2010 S Promote unrelated product	FTC investigation

Drug	US Sales	Parties	Agreement		Antitrust activity
AndroGel *Testosterone gel 1%*	$330 m	Solvay-Watson	Sept. 2006	$ Cash $ 180 days by contract Δ Neutralize first filer Δ Entry in Aug. 2015 S Promotion	None
		Solvay-Par (L)	Sept. 2006	$ $60 million Δ Entry in Feb. 2016 S Promotion S Backup manufacturing	
Imitrex Tablets *Sumatriptan succinate*	$890 m	Glaxo-Dr. Reddy's	Oct. 2006	$ Exclusive auth'd generic Δ Neutralize first filer S Entry in late 2008	None
Imitrex Injection *Sumatriptan succinate injection*	$220 m	Glaxo-Spectrum	Nov. 2006	$ Exclusive auth'd generic Δ Neutralize first filer Δ Entry in Aug. 2008	None
Wellbutrin XL *Bupropion HCl extended release*	$1,467 m	Biovail-Teva	Mar. 2007	$ Damage waiver, 300 mg $ Product supply $ No AG, 150 mg Δ Entry in 2008, 150 mg	None
		Biovail-Watson (L)	Mar. 2007	$ Cash from separate suit Δ Entry in 2007, 300 mg	

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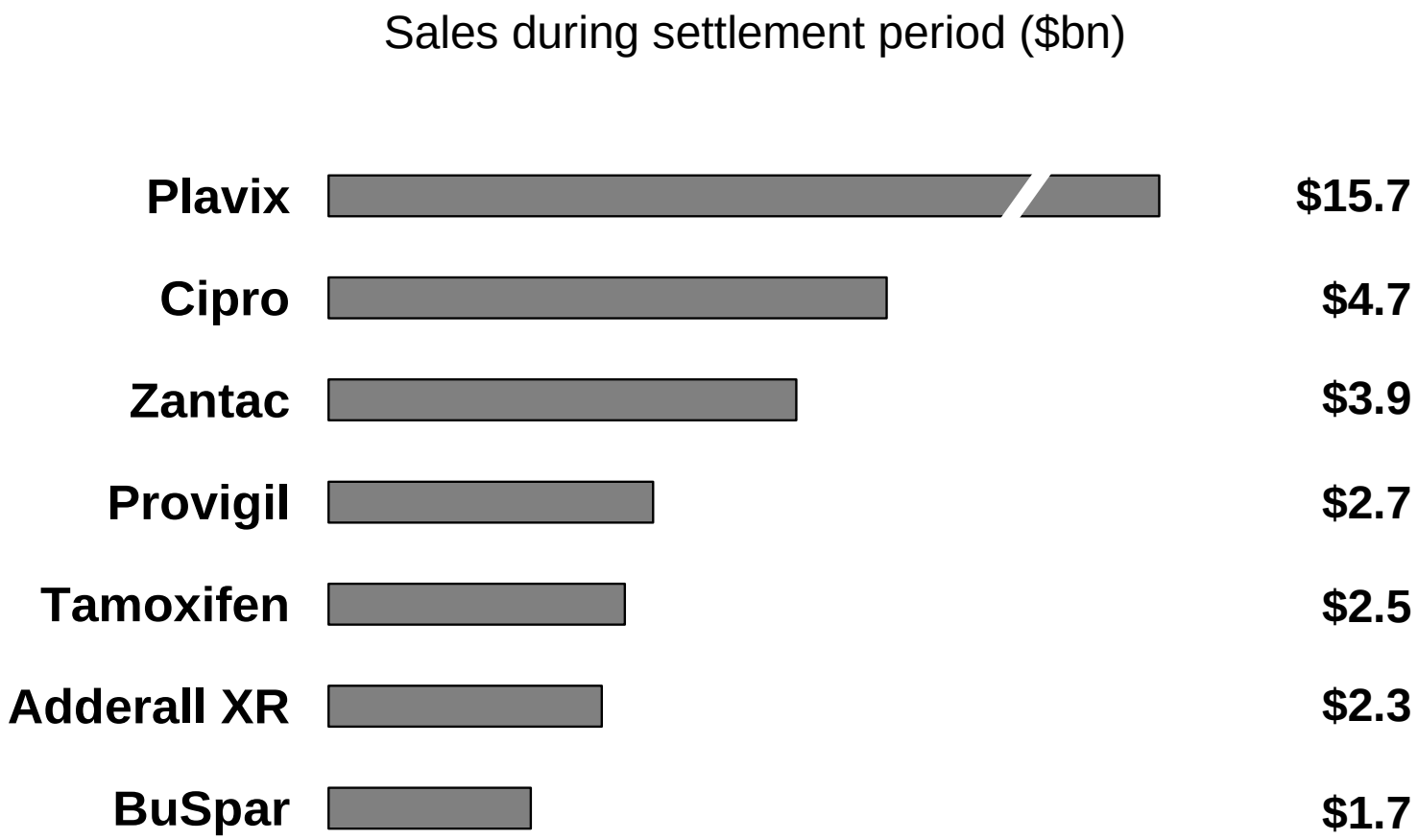

Assumes constant sales during settlement years; no inflator applied to make dollars constant; Plavix agreement never implemented

JUNK – not part of presentation – data only