

A Wall Street Perspective on Generics

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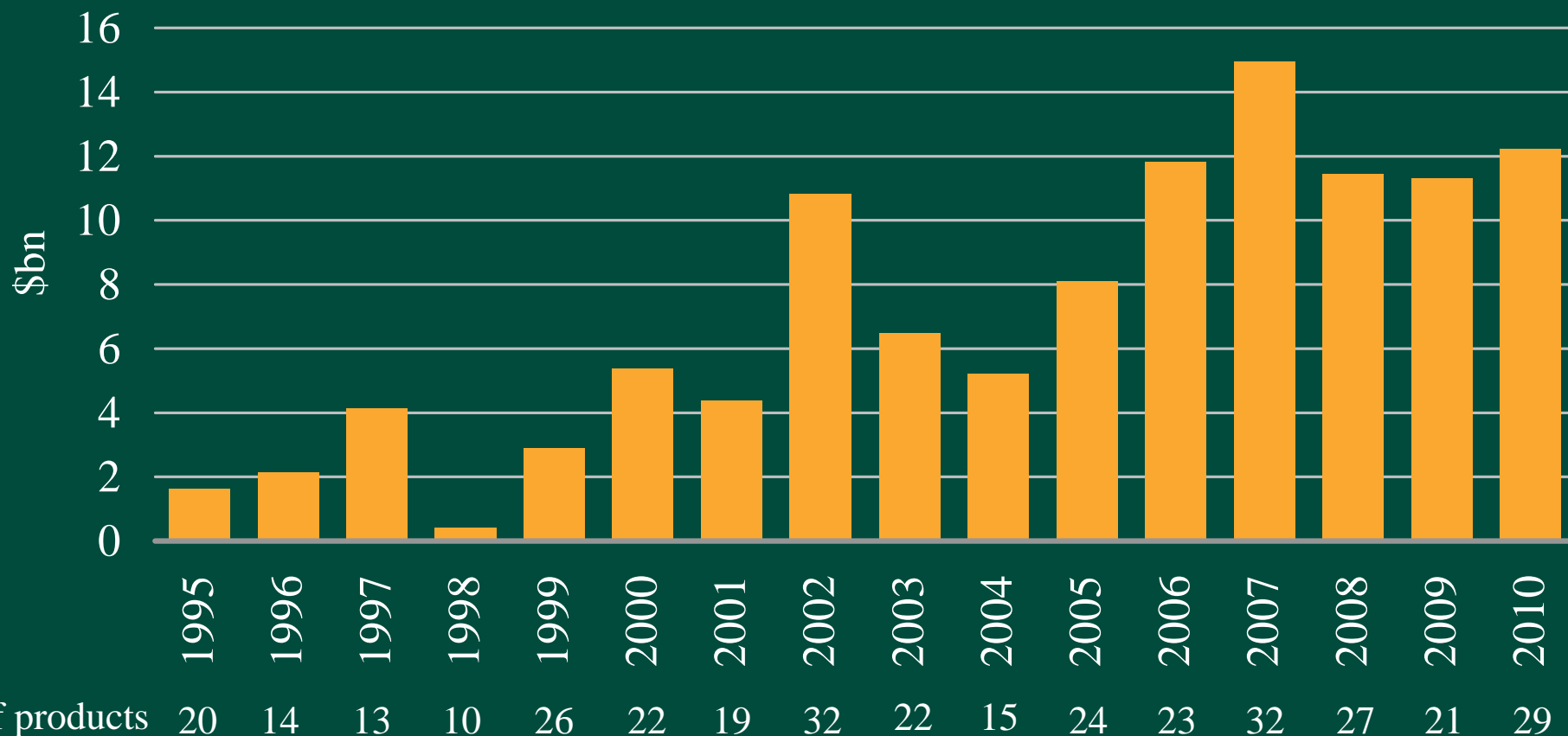
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Generic Industry – Key Trends

- ◆ Major wave of patent expirations continues
- ◆ Industry consolidation
- ◆ Relative pricing stability
- ◆ Pricing alone no longer sufficient competitive advantage
- ◆ More rapid rate of generic penetration in post-Prozac era
- ◆ Barriers to entry – increasingly difficult to dislodge market leaders
- ◆ Increasing generic utilization push from customers - i.e. retailers, PBMs, government
- ◆ Brand defense strategy remains ongoing challenge

Patent Expirations – Key Growth Driver

Dollar value of all products going off patent 1995–2010



Source: Lehman Brothers.

- ◆ Sizeable increase for 2006-2010 (~\$62B) vs. 2001–2005 (~\$35B) vs. 1996–2000 (~\$15B)

Key Generic Opportunities – Outlook Remains Robust

2006			2007			2008		
Products	Sales (\$M)	Generic	Products	Sales (\$M)	Generic	Products	Sales (\$M)	Generic
Pravachol	\$1,310	TEVA, WPI	Wellbutrin XL 300mg	\$1,000	Anchen, IPXL/TEVA	Zyrtec/D *	\$1,640	Unidentified P4 filer (Mar-05/Jun-04)
Zocor	\$3,200	TEVA, Dr. Reddy's	Zofran ODT*	\$275	PRX/BRL	Dekapote ER	\$930	MYL
Zoloft	\$2,580	TEVA, Greenstone	Norvasc	\$2,120	MYL, Greenstone	Camptosar	\$530	WPI, Greenstone
Proscar	\$400	TEVA, Dr. Reddy's	Lortrel	\$1,500	TEVA, Sandoz	Fosamax weekly	\$1,950	TEVA & BRL
Flonase	\$740	Roxane, PRX	Toprol XL 50mg	\$600	WPI/Sandoz, PRX	Requip	\$200	TEVA
Ditropan XL	\$380	MYL, IPXL/TEVA	Toprol XL 100&200r	\$800	KV Pharma, PRX	Effexor XR	\$2,450	TEVA
Actiq	\$450	BRL	Coreg	\$1,310	TEVA	Wellbutrin XL 150n	\$800	Anchen, IPXL/TEVA
Toprol XL 25m	\$300	Sandoz, PRX	Skelaxin	\$400	Sandoz, PRX	Risperdal	\$2,420	MYL & Dr. Reddy's (both claim FTF status)
			Concerta	\$800	IPXL/TEVA, WPI	Lamictal	\$1,700	TEVA
			Allegra D	\$340	BRL	Kytril	\$160	TEVA
			Lovenox	\$1,620	Amphastar/WPI, TEVA	Altace	\$720	Cobalt
						Cosopt / Trusopt	\$400	Hi-Tech & Apotex (pot. shared exclusivity)
						Imitrex	\$800	Dr Reddy's
						Prograf	\$540	No PIV filer, no tentative approvals
Total:	\$9,360		Total:	\$10,765		Total:	\$15,240	

* Dec 2006 generic launch

Sources: Lehman Brothers, company reports, FDA website, IMS.

* Dec 2007 generic launch

Note: P4 stands for Paragraph 4

- ◆ Key generic opportunities = meaningful benefit to few generic companies as a result of limited competition arising from 180-day exclusivity and/or other barriers to entry

Generic Industry Consolidation

Industry Consolidation

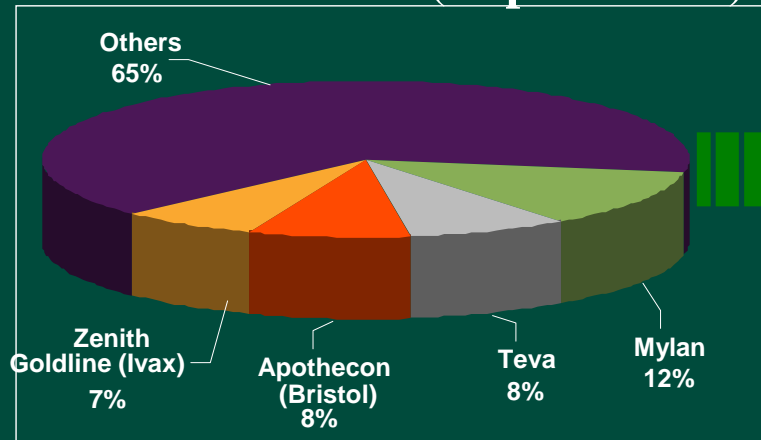
Major Generic Mergers 1994 – 2007

1994	Ivax – Zenith
1996	Teva – Biocraft
1997	Watson – Royce
1998	Watson – Rugby
1999	Teva – Copley
2000	Watson – Schein
2001	Teva – Novopharm, Alparma – Faulding
2004	Teva – Sicor
2005	Sandoz – Eon Labs, Teva – Ivax
2006	Watson – Andrx, Barr – Pliva
2007	Mylan – Matrix 72% stake & Merck Generics (pending), Sun Pharma – Taro Pharma (pending)

Notable Brand Company Exits From Generic Business 1994 – 2002

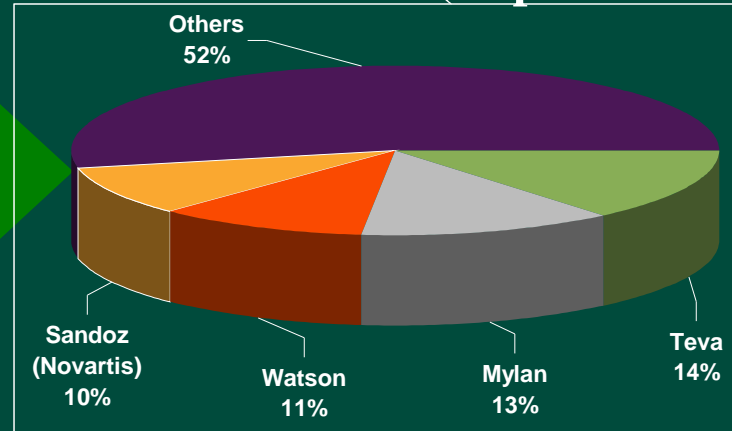
Merck
 Syntex
 Warner Lambert
 Aventis
 American Cyanamid (merged with AHP)
 Bristol-Myers Squibb
 Wyeth

IMS MAT Jun-97 (Top 4 = 35%)



Source: IMS Health

IMS MAT Mar-05 (Top 4 = 47%)





Generic Industry – Pricing Environment

- ◆ Negatives

- Increasing competition on older products
- Fewer opportunities to raise prices

- ◆ Positives

- Over last 10+ years, relative pricing stability from industry consolidation
- Remaining competitors more rational
- Going forward, large volume increases should lessen pricing pressure on base products – evidence during last 6-8 months?

Generic Industry – Accelerating Rate of Generic Penetration

- ◆ Successful generic substitution today – 80% conversion within 4-6 weeks, compared to 60% within 6-8 months just a few years ago
- ◆ Drivers of rapid penetration include:
 - HMO/PBM tiered co-pays and widening gap between tiers
 - Drug retailers’ increased focus on aggressive generic substitution with higher profitability a key factor

Retail Profitability – Brand vs. Generic Drugs

Third Party Prescription	Branded	Generic
AWP for a branded drug and MAC for a generic	\$60.0	\$20.0
Cost to Retailer to Acquire Drug	AWP – 22%	MAC – 50%
	= \$46.8	= \$10.0
Reimbursement to Retailer	AWP – 12%	MAC
	= \$52.8	= \$20.0
Plus Dispensing Fee	+ \$1.75	+ \$1.75
	= \$54.6	= \$21.8
Gross Profit Dollars	\$7.8	\$11.8
Gross Margin (including dispensing fee)	14.2%	54.0%
Dispensing cost (O&A)	\$7.26	\$7.26
Operating Income	\$0.49	\$4.49
Operating Margins	0.9%	20.6%

Source: Lehman Brothers.

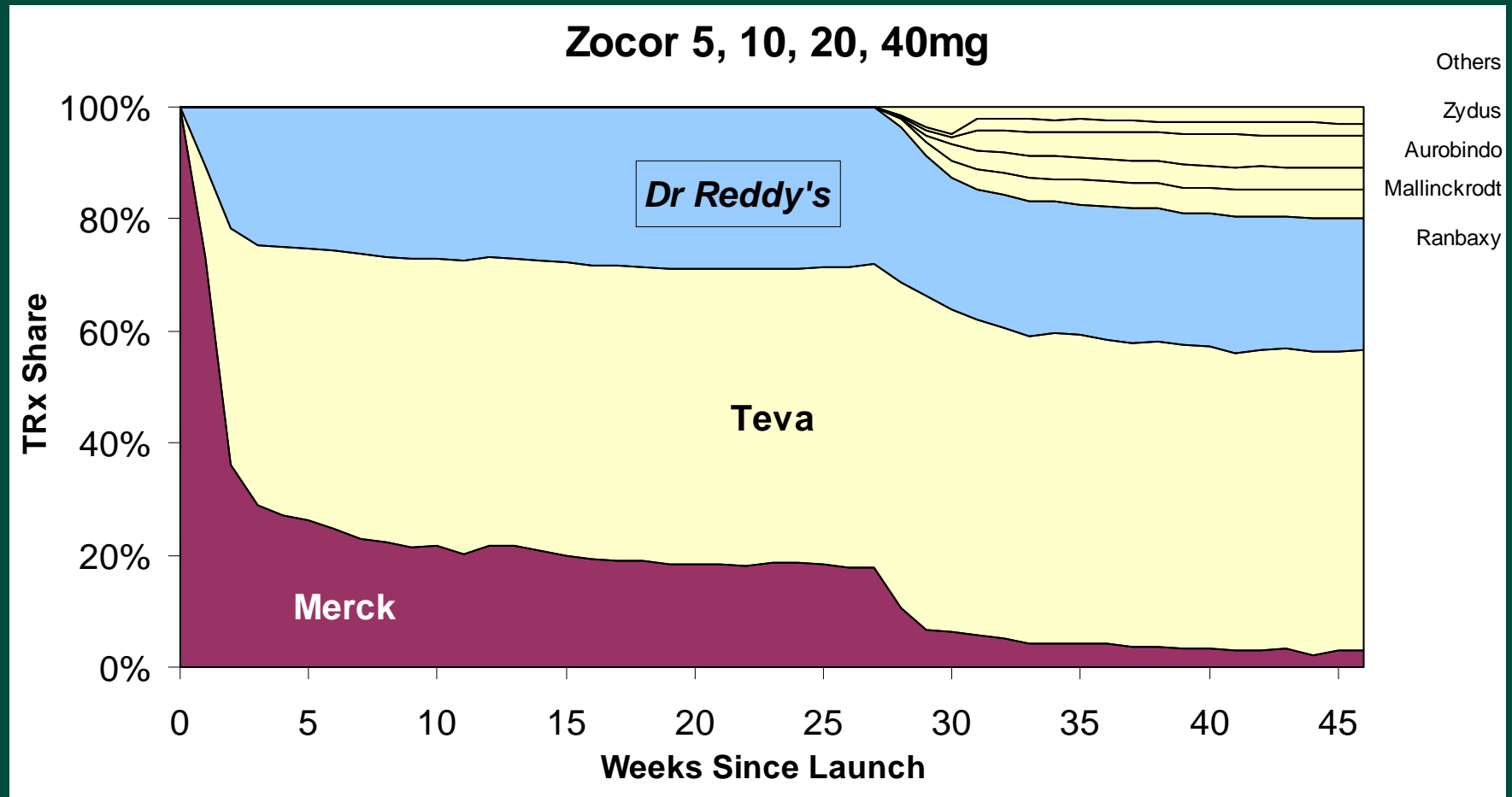
Generic Industry – Competitive Advantages: New Product Development

- ◆ API sourcing
 - Consistent, early and reliable access to raw materials
 - Non-infringing APIs
- ◆ Legal acumen
 - Evaluate IP estate of new products early in selection process
- ◆ Scientific know-how
 - Formulation expertise & technology platform – development of non-infringing products
- ◆ Regulatory expertise
 - Quality of ANDAs and manufacturing facilities

Generic Industry – Competitive Advantages: Distribution

- ◆ Pricing alone no longer sufficient competitive advantage
 - generics competing more rationally
 - lower pricing ultimately does not lead to market share gain
- ◆ Sustainable competitive advantages – ensure customers will have uninterrupted supply of products when needed
 - consistent & reliable customer service
 - capacity to meet demand
 - breadth & quality of product portfolio
 - depth & breadth of ANDA pipeline
 - speed to market on new products
- ◆ Balance between pricing strategy and market share goal

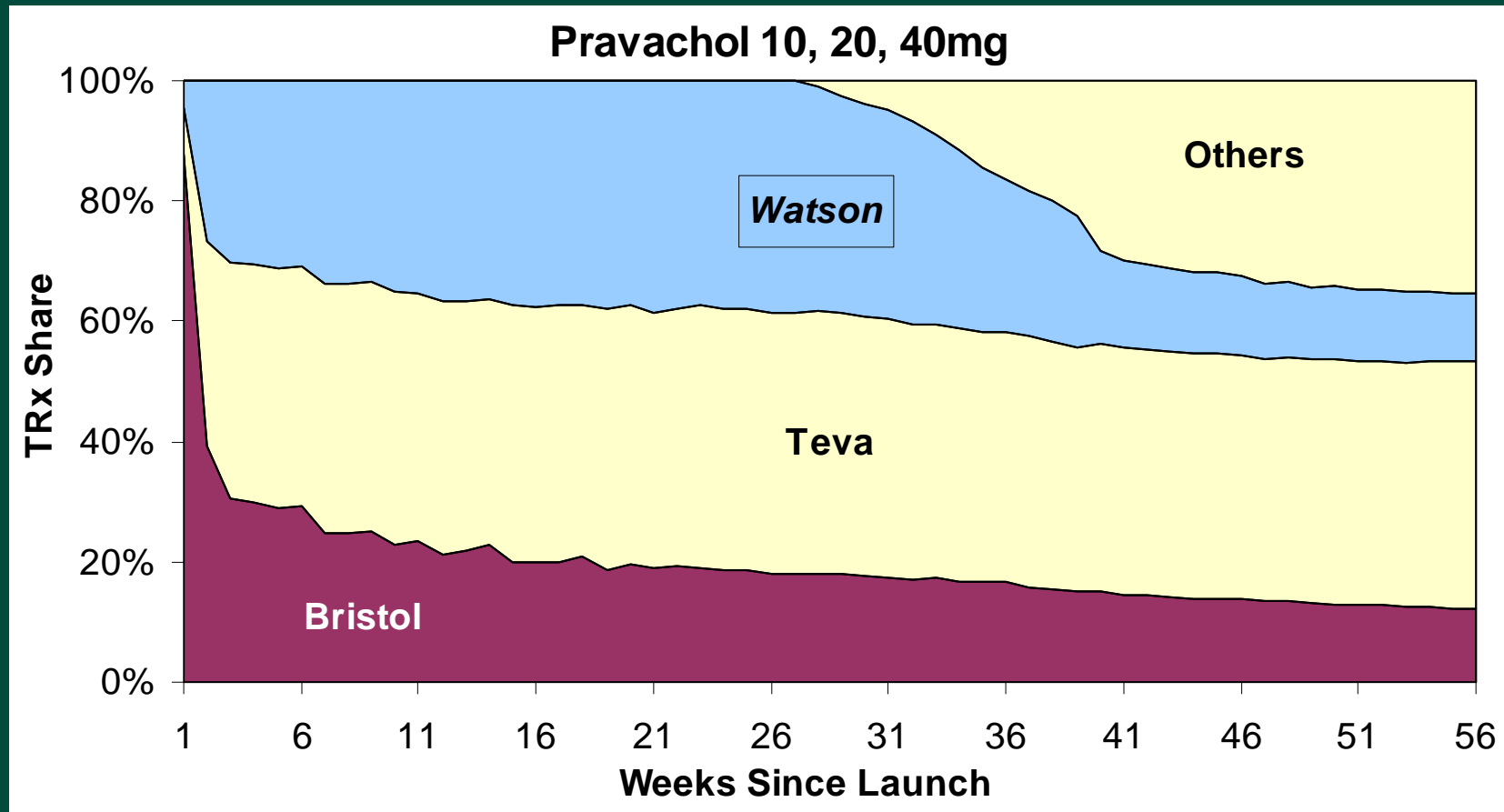
Generic Industry – Competitive Advantages: Distribution



Source: IMS Health.
First generics launched in June 2006.



Generic Industry – Competitive Advantages: Distribution

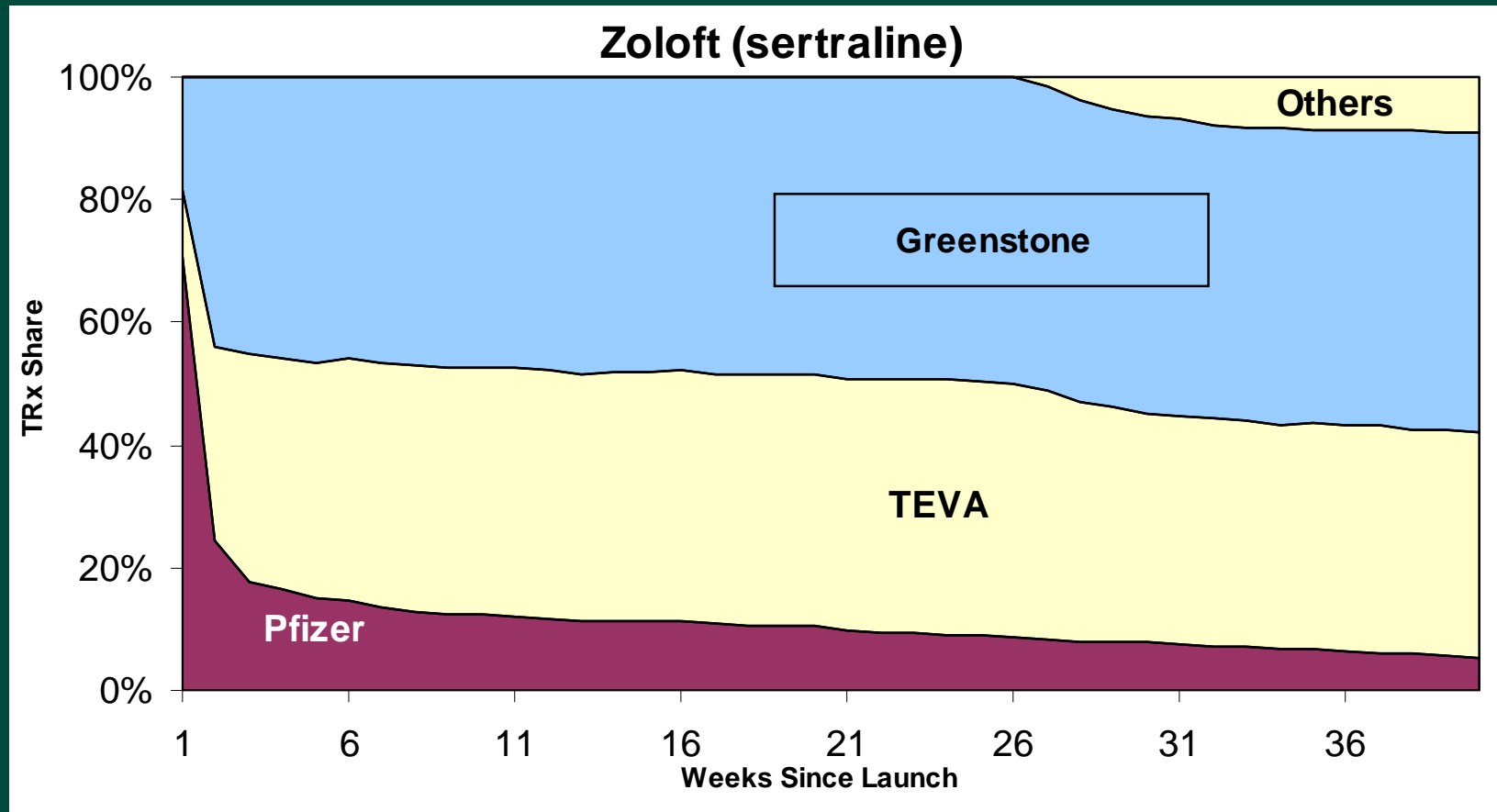


Source: IMS Health.

First generics launched in April 2006.



Generic Industry – Competitive Advantages: Distribution



Source: IMS Health.
First generics launched in August 2006.





Brand Companies Defense Strategies

- ◆ Patent litigation
- ◆ Citizen petitions
- ◆ Authorized generics
- ◆ Reformulations ahead of patent expiry

Brand Companies Defense Strategies

Patent Litigation

- ◆ Number of Orange Book-listed patents have increased significantly from average of 2 per drug to average of 10 per drug in the last 10 years

Patent Type	Key Claims / Orange Book	Patent Challenge
Composition of matter	<ul style="list-style-type: none">◆ Drug substance and molecular structure◆ Orange Book listing	<ul style="list-style-type: none">◆ Strongest – virtually impossible to non-infringe and very difficult to invalidate
Formulation	<ul style="list-style-type: none">◆ Physical composition or delivery mechanism◆ Orange Book listing	<ul style="list-style-type: none">◆ Invalidity (grounds of obviousness) or non-infringement
Process	<ul style="list-style-type: none">◆ Procedure for making drug◆ Typically not Orange Book listed but claims included in other patents	<ul style="list-style-type: none">◆ Invalidity (grounds of obviousness) or non-infringement
Use	<ul style="list-style-type: none">◆ Treatment of specific diseases◆ Orange Book listing	<ul style="list-style-type: none">◆ Relatively weak form of patent – invalid or non-infringement

Source: Lehman Brothers.

- ◆ Questionable patents include metabolite, polymorph, product-by-process, drug intermediates, and any that does not claim FDA-approved use

Brand Companies Defense Strategies

Citizen Petitions

- ◆ Formal protests to the FDA in an attempt to prevent or delay approval of competing products, new or generic
- ◆ Commonly cite violations in FDA requirements, policy or procedures
- ◆ Can be very effective blocking tactics
- ◆ FDA required to carefully consider petitions
- ◆ Petition backlog continues to grow
- ◆ Legislative fixes to curb abuses appear unlikely over near-term

Brand Companies Defense Strategies

Authorized Generics

- ◆ Diminished generic benefit of 180-day exclusivity
- ◆ Likely here to stay although future legislative fixes remain uncertain
- ◆ Lower growth impact reflected in forecasts

Brand Companies Defense Strategies

Authorized Generic Deals – Past

- ◆ In the past, typically resulted from innovators and generic companies settling patent litigation
 - Generic company allowed to launch drug manufactured by innovator earlier than on own
 - May limit downside risk to innovator
 - Does not add generic competition since deal is more often with first-to-file generic

Brand Companies Defense Strategies

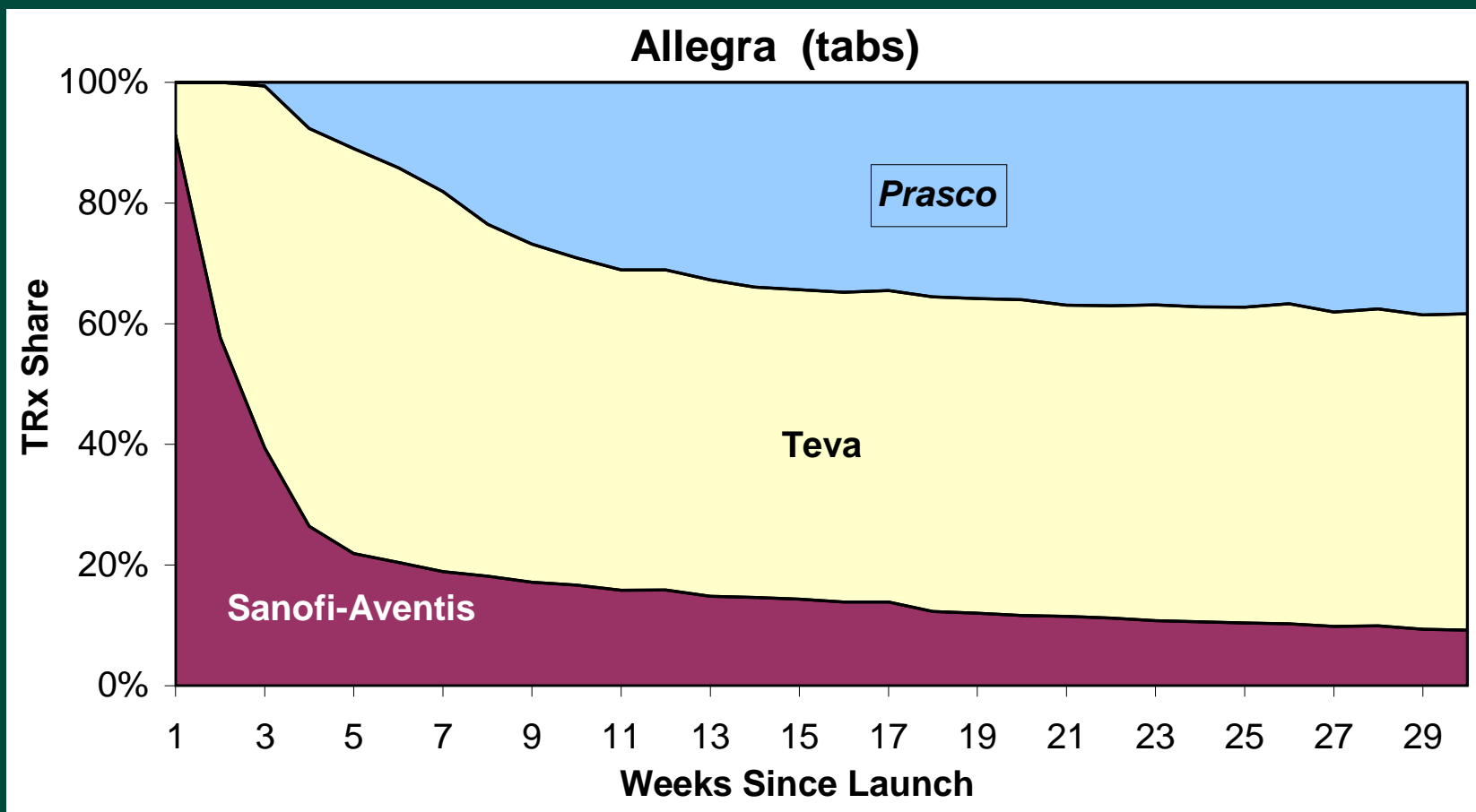
Authorized Generic Deals – Present

- ◆ Currently, witnessing deals between innovators and generic companies with and without patent litigation
 - Generic company launches with drug manufactured by innovator with timing triggered by first launch of another generic (“true” generic)
 - May limit downside risk to innovator
 - Adds a competitor during period that would have been exclusive to one generic (first-to-file)

Authorized Generic Deals – Innovator Perspective

- ◆ When might a deal make economic sense for innovator?
 - Expect rapid generic penetration by first generic to market
 - Envision modest competition post 180-day exclusivity
 - Manufacturing facilities require support (coverage of fixed costs)
 - Brand positioning and life cycle management

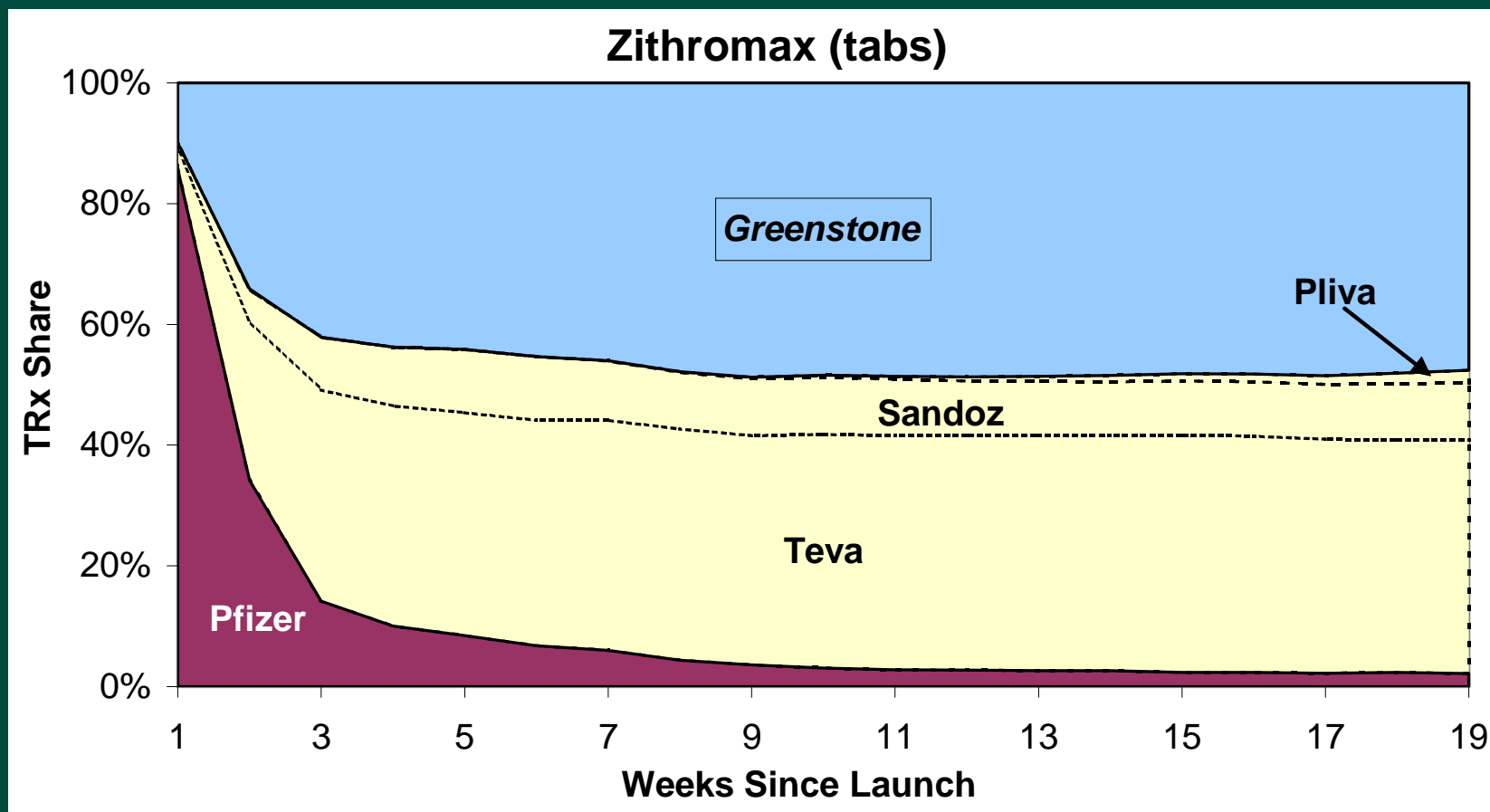
Authorized Generics – What Do Case Studies Show?



Source: IMS Health.
First generics launched in September 2005.



Authorized Generics – What Do Case Studies Show?

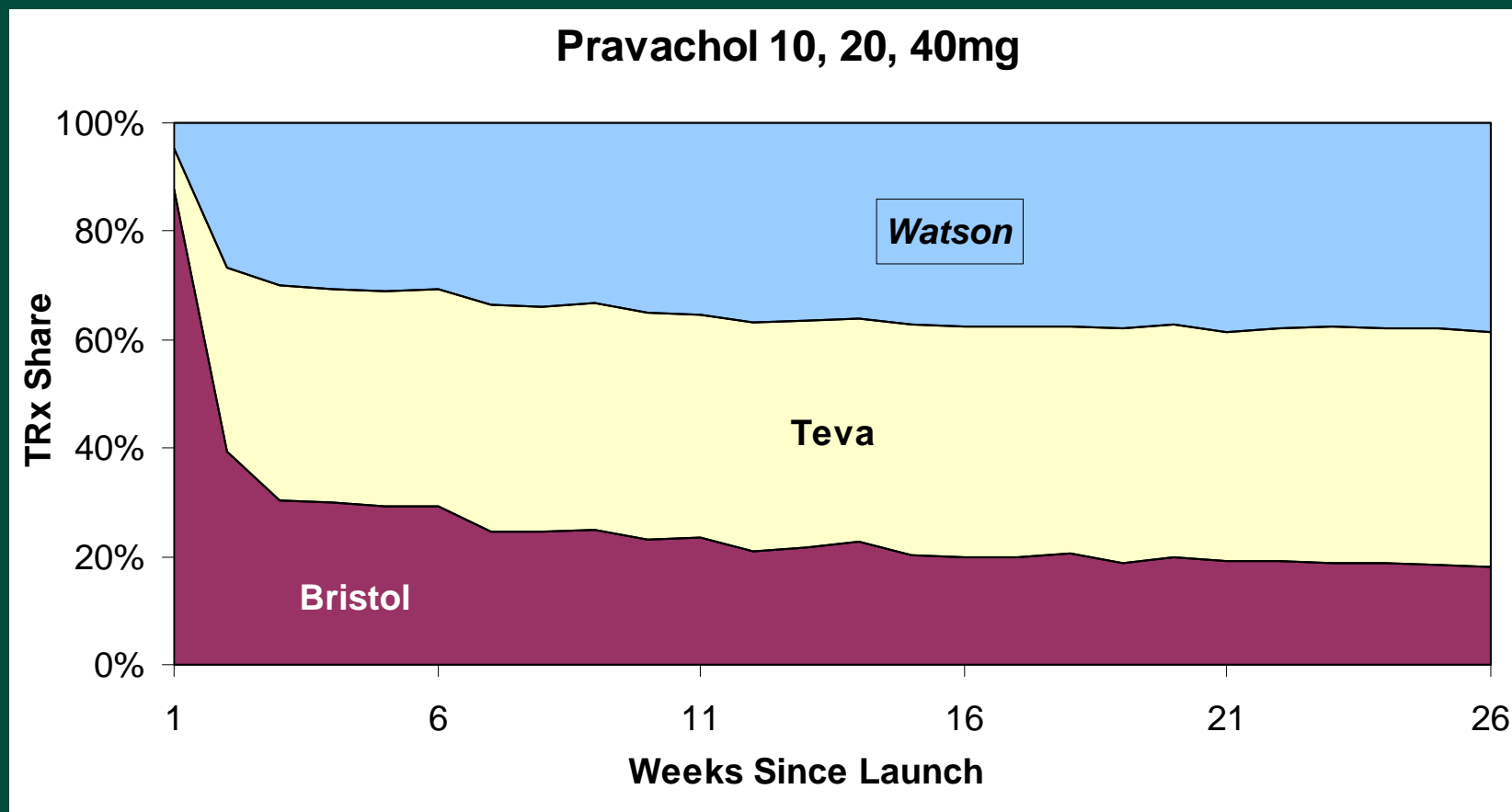


Source: IMS Health.

First generics launched in December 2005.



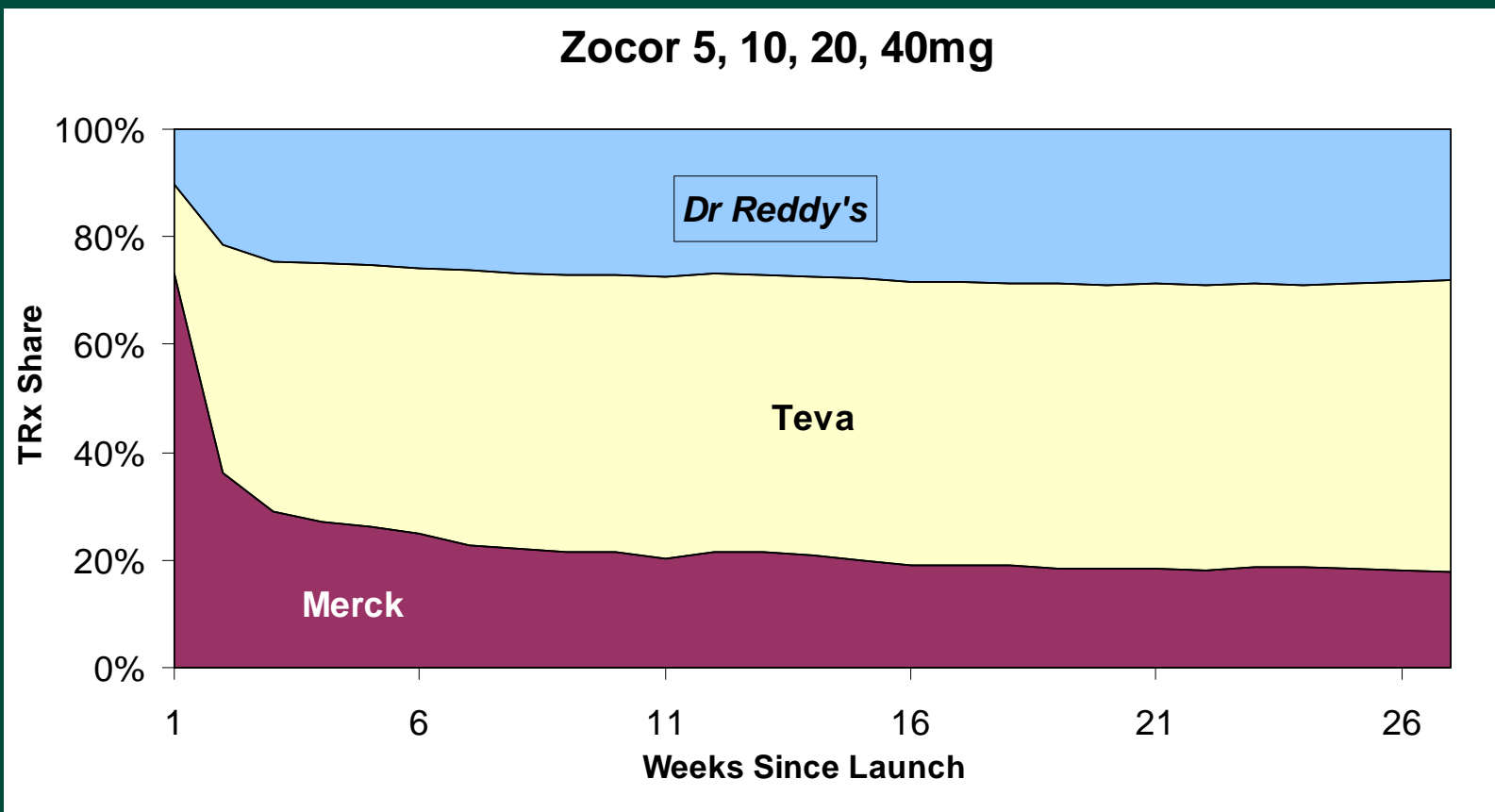
Authorized Generics – What Do Case Studies Show?



Source: IMS Health.
First generics launched in April 2006.

brand ANDA generic authorized generic or brand generic

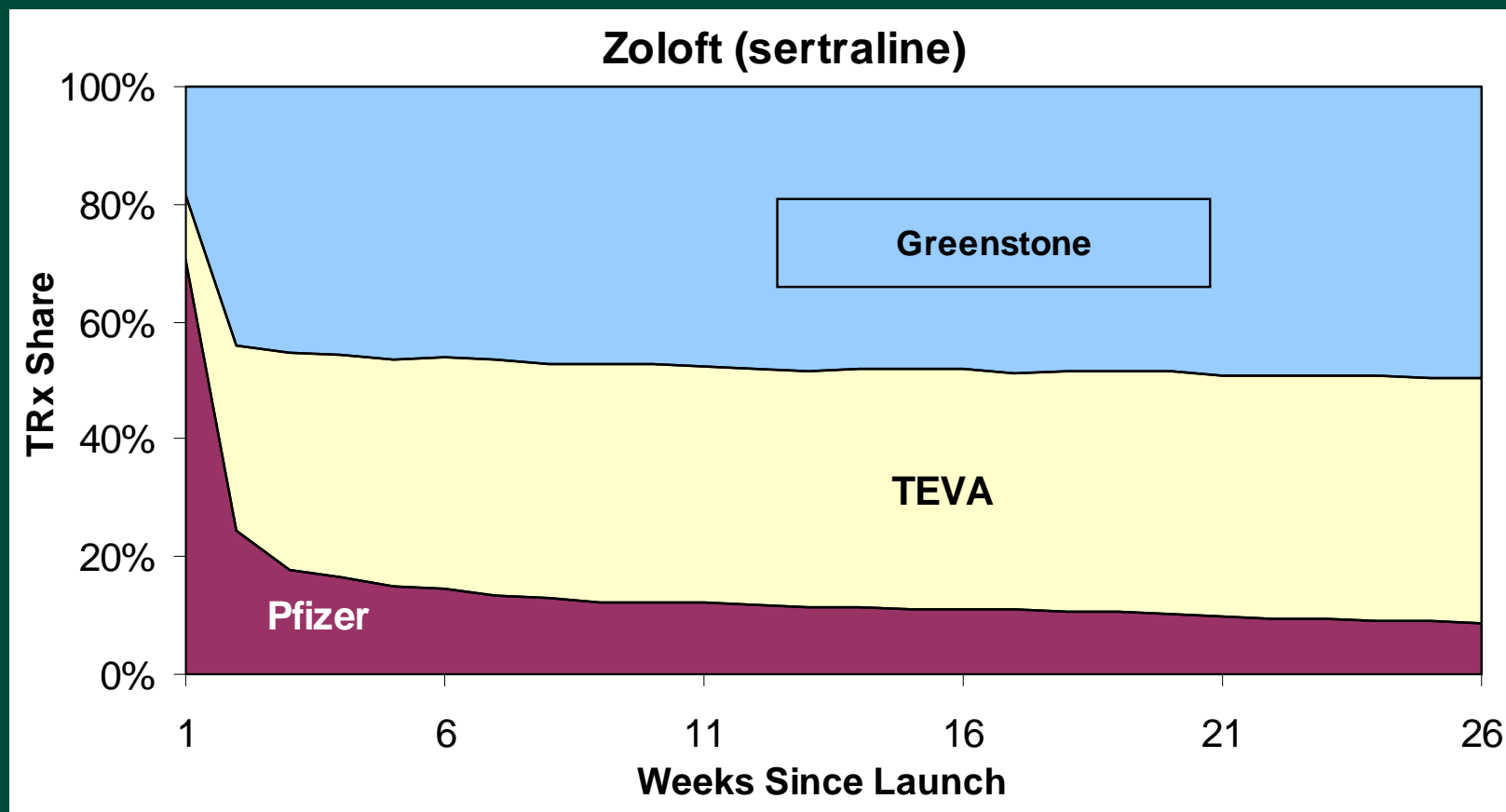
Authorized Generics – What Do Case Studies Show?



Source: IMS Health.
First generics launched in June 2006.



Authorized Generics – What Do Case Studies Show?



Source: IMS Health.
First generics launched in August 2006.



Authorized Generics – Our Take-Aways

- ◆ Dominant generic players are expected to continue to capture the lion's share of the market
- ◆ Generic companies most affected likely to include those with modest distribution capabilities and whose first-to-files represent large percentage of ANDA filings
- ◆ Authorized generics launched through subsidiaries of brand companies in absence of broad product line
 - less likely to capture major share
 - could more significantly drive down value though little evidence of this
- ◆ Lower growth impact reflected in our forecasts & valuation

At Risk Launches vs. Legal Settlements

Key At-Risk Launches			Key Settlements			
Generic	Product	Year	Generic	Brand	Product	Year
Mylan	Prilosec	2003	Mylan	Johnson & Johnson	Ditropan XL	2005
Apotex	Paxil	2003	Teva	Wyeth	Effexor XR	2005
Eon	Wellbutrin SR	2004	Teva	GlaxoSmithKline	Lamictal	2005
Ivax, Teva & Alparma	Neurontin	2004	Alphapharm	Forest	Lexapro	2005
Teva & Barr	Allegra	2005	Barr	Kos Pharmaceuticals	Niaspan	2005
Apotex*	Plavix*	2006	Barr, Teva, Mylan & Ranbaxy	Cephalon	Provigil	2005
Teva	Lotrel	2007	Cobalt	King Pharmaceuticals	Altace	2006
			Barr & Impax	Shire	Adderall XR	2006
			Apotex*	Bristol-Myers & Sanofi*	Plavix*	2006
			Dr Reddy's	Merck	Propecia	2006
			Par & Watson	Unimed	Androgel	2006

* Settlement eventual failure was followed by at-risk launch in August 2006, which was then blocked by a preliminary injunction on 9/1/06.

Sources: Lehman Brothers, company reports.

At Risk Launches vs. Legal Settlements

- ◆ Increase driven by more litigation today than earlier period, owing to more patents per drug
- ◆ Generics have greater financial resources and legal expertise
- ◆ Settlement may have become more attractive, due to authorized generics and the associated diminished value of 180-day exclusivity
- ◆ Case-by-case analysis still required to determine outcome
 - Relative strength of each side's case
 - Relative financial & strategic importance of product to each side

Regulatory Outlook – Will Washington Come Through?

- ◆ In our view, the generic industry faces best political environment since early 90's
- ◆ Key areas receiving significant attention:
 - Generic biologics
 - Citizen petitions
 - Reverse settlements
 - Authorized generics
 - Generic drug FDA user fees
- ◆ Democratic control of Congress improves prospects for legislation becoming law
- ◆ More of benefit from headlines than significant potential policy change
- ◆ We place a 40% probability of at least one type of generic reform being enacted, but must be in 2007

Reformulations To Stay Ahead Of Generics

“Traditional” Drug Delivery

- ◆ Extended-release, transdermal patches, etc.
- ◆ Protected by three years HW exclusivity and **delivery system patents**
- ◆ Clever generic companies may successfully engineer around patents (e.g. Andrx)

Newer Approaches to “Reformulation”

- ◆ Single isomer, active metabolite, isomer of metabolite
- ◆ Protected by three or five years HW exclusivity and possibly **composition of matter patents**
- ◆ Offer greater protection with potential for shorter development timetable

Source: Lehman Brothers.

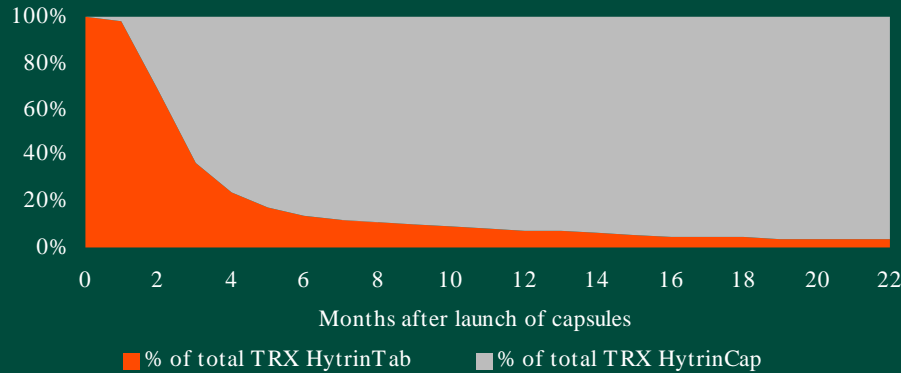
Swing Factors Driving Success of Reformulation Strategies

- ◆ Launch date of reformulation relative to generic entry date for parent compound
- ◆ Clinical advantages of reformulation
- ◆ Nature and promotion sensitivity of drug compound/category
- ◆ Pricing

Reformulation Defense Strategies

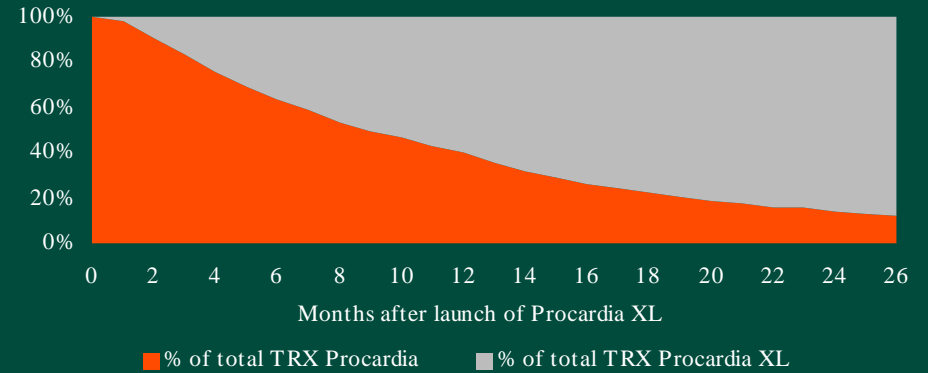
Case Study #1 - Hytrin tablets to capsules

% TRX:
Hytrin Tab/Hytrin Cap split



Case Study #2 – Procardia to Procardia XL

% TRX:
Procardia/XLS split



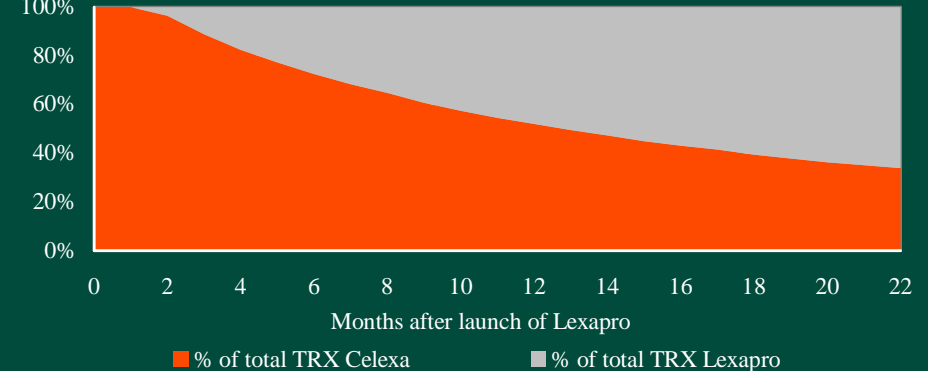
Case Study #3 – Glucophage XR & Glucovance

% TRX:
Glucophage XR/Glucovance split



Case Study #4 – Celexa to Lexapro

% TRX:
Celexa/Lexapro split

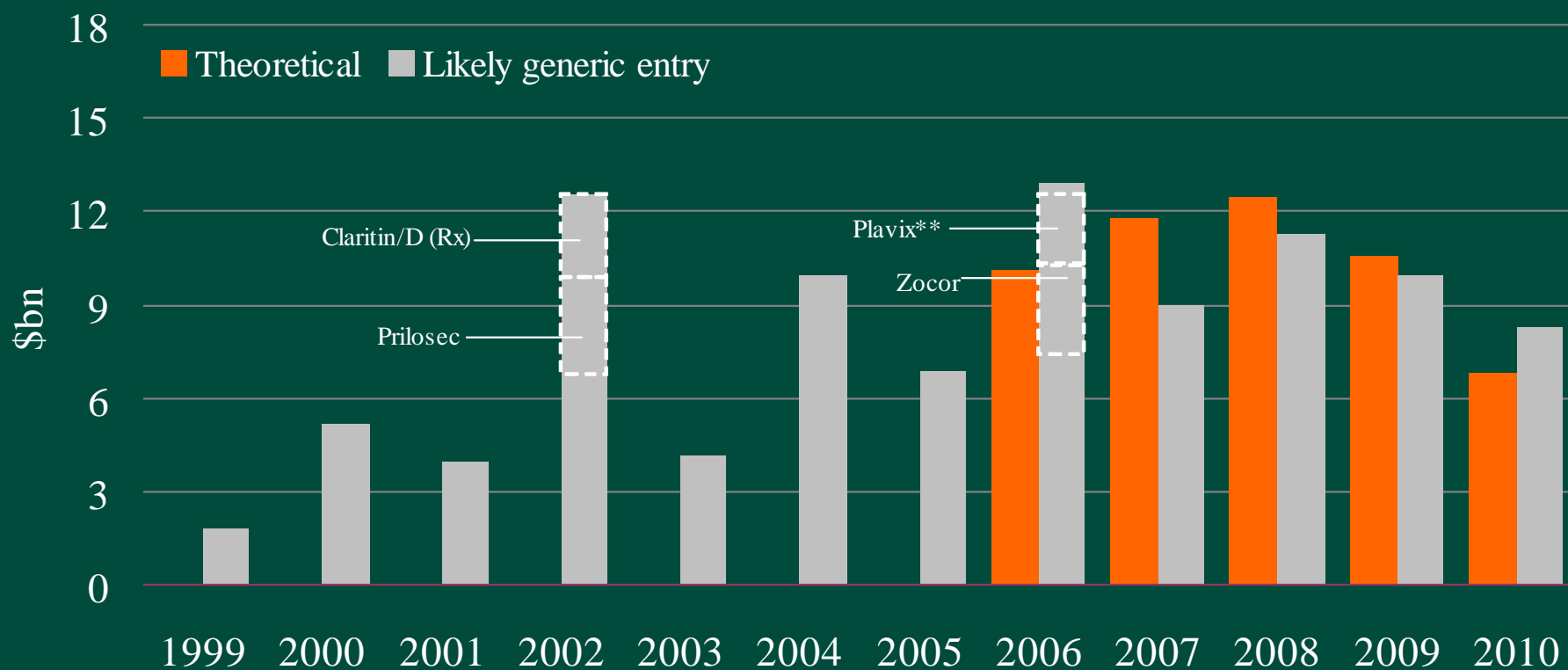


*Glucovance was launched in August 2001 and Glucophage XR was launched in October 2001
Source: IMS and Lehman Brothers.

Lexapro was launched in August 2002

US Patent Expirations – Spring '07 Outlook

Dollar value of blockbuster* products going off patent 1999–2010 (“official”/theoretical dates vs. likely generic entry)



■ # of products

■ # of products

Year	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
# of products (Theoretical)	0	0	0	0	0	0	0	13	13	14	14	10
# of products (Likely generic entry)	1(A)	10(A)	4(A)	13(A)	10(A)	15(A)	11(A)	10(A)	9	14	15	10

* blockbuster defined as products with annual sales >\$150M at time of patent expiration/generic entry

** Generic Plavix was launched but subsequently forced to stop selling by a preliminary injunction order.

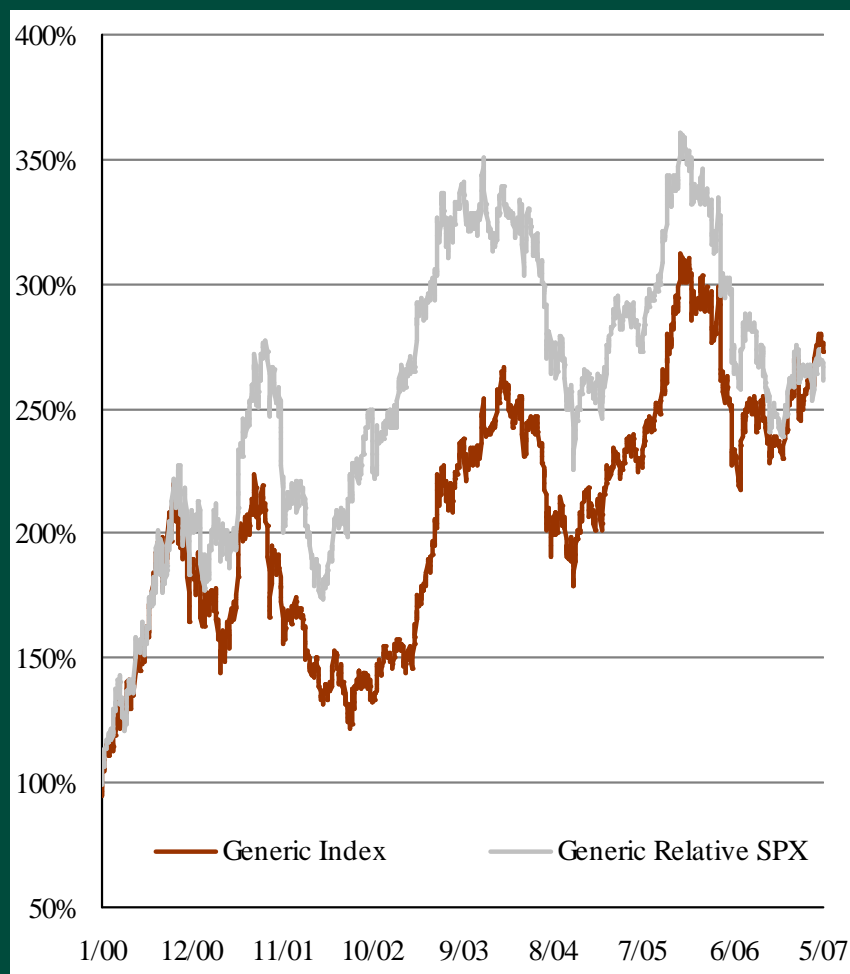
Source: Lehman Brothers.

Generic Industry – Key Future Trends

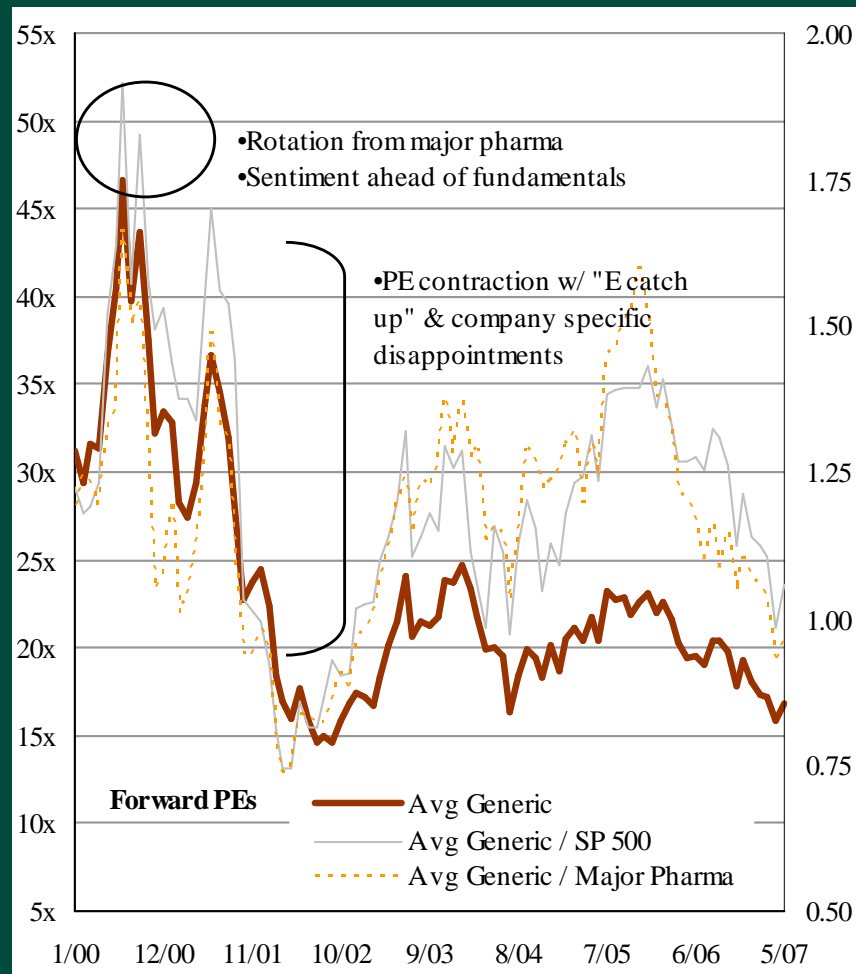
- ◆ Large wave of patent expirations should provide attractive opportunities
- ◆ Price stability remains in place
- ◆ Rapid generic penetration likely to continue
- ◆ API sourcing likely to become increasingly important, potentially leading to more strategic alliances or greenfield efforts at backward integration
- ◆ Authorized/brand generics likely to diminish profitability for first-to-file generics
- ◆ Patent litigation likely to remain active as generic company legal resources and sophistication continue to grow
- ◆ Longer-term
 - Consolidation and/or alliances should continue
 - Innovator industry's woes could potentially become generics' problem
 - Generic biologics – next potential big opportunity, but we see few with capability to compete

Performance & Valuation – Generic*

Price Performance



Historical Valuation



Generic Index includes ADRX, ALO, BRL, IVX, MYL, TARO, TEVA and WPI
Source: Facset and Lehman Brothers

Our Investment Approach & Outlook

- ◆ Initial premise: “buy & hold” strategy challenging due to generics’ inherent limited pipeline visibility
- ◆ Evaluation parameters
 - Management strength: long-term strategy; daily execution; communication with investors
 - ANDA pipeline: size relative to base; disclosed products
 - Earnings base & outlook: degree of diversification
- ◆ Trading opportunities remain in leveraged plays
- ◆ Strong fundamental outlook for industry
- ◆ Future forecast stock performance – earnings growth with modest multiple expansion

US Generic Pipelines Summary

	<i>ANDAs Pending</i>	<i>Value \$Billions</i>	<i>Number FTF</i>	<i>Value \$Billions</i>
Teva	151	\$90	42	\$35
Ranbaxy	88	56	20	25
Watson	70	53	12	
Dr. Reddy's	69	56	18	
Mylan	62	49	14	11
Barr	60	30		
Par	48	21	8	1-
Abraxis	29	2		
Impax	21	8		

Sources: Lehman Brothers estimates, company reports.

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