

Institutional Cross-holdings and Generic Entry in the Pharmaceutical Industry

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Motivation

Firms controlled by common owners lack incentives to compete

- Benefit of competing aggressively to one firm hurts other firms' value in the same investors' portfolio
 - ▶ Rotemberg (1984), Admati, Pfleiderer, and Zechner (1994), O'Brien and Salop (2000), Gilo, Moshe, and Spiegel (2006), Azar (2012, 2017)
- BlackRock, Vanguard and State Street hold 88% of S&P 500

Asset managers engage with portfolio firms "behind the scenes"

- Voice, CEO pay, voting rights
- Comparable to J.P. Morgan and John D. Rockefeller
- Passive investment strategy \neq passive owners

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Azar, Schmalz and Tecu (2017): airline industry

- Measure market concentration index that takes into account who owns the competitors
 - ▶ Modified Hirschman-Herfindal Index (MHHI)
 - ▶ Non-linear combination of product market shares and institutional ownership
- Air ticket prices increased by 3–12%

Spurious correlation in *post-entry* setting

$$\hat{\alpha} = \frac{\text{Cov}(\text{MHHI}, \text{Price})}{\text{Var}(\text{MHHI})} > 0$$

- MHHI depends on (1) common ownership and (2) product market shares (HHI)

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What We Do & What We Find

If common owners care about joint profits of the industry, do they block product market entrants?

- Pre-entry game between (1) brand-name pharmaceutical companies (*incumbent*) and (2) generic drug manufacturers (*entrant*)
- Brand files patent infringement lawsuit against generics
- Generic shareholders' ownership in brand v.s. their ownership in generic

Anticompetitive effects of common ownership

- Brand and generic enter into "pay-for-delay" settlements
- Generic entries are delayed

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Plan for the Talk

- Empirical Strategy
- Institutional Setting
- Data/Sample
- Institutional Cross-holdings and Settlement
- Anticompetitive Effects of Settlement
- 180 Day Marketing Exclusivity

Empirical Strategy

Common owners' wealth **after entry occurs**

$$\Delta W = (\alpha_b + \alpha_g) \left(\frac{\alpha_b}{\alpha_b + \alpha_g} \Delta \text{brand value} \downarrow + \frac{\alpha_g}{\alpha_b + \alpha_g} \Delta \text{generic value} \uparrow \right)$$

- Top N generic shareholders' ownership in the brand (α_b) relative to their ownership in the generic (α_g) (Harford, Jenter and Li, 2011)
- Does NOT depend on HHI!!

Collusion = $\beta \times$ Top N generic shareholders' weight in brand + u

- Fixed-effect panel regressions: omitted variables
- Panel IV (Mutual fund scandal): reverse causality

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Generic Entry under Hatch-Waxman Act of 1984

Sell generic drugs **before** patent expirations

- Submit Paragraph IV application to FDA
- Argue patents covering a branded drug are not valid

Brand-name company

- File a patent infringement lawsuit
- "Pay-for-delay" settlements
 - ▶ Anticompetitive under imperfect FTC monitoring

180 day marketing exclusivity

- First generic that successfully defends
- Exploited by brand to deter all generic entries

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Pfizer (brand) vs. Ranbaxy (generic)

Pfizer's Liptor

- World's most-prescribed drug (cholesterol-lowering)

August 19, 2002: Ranbaxy challenged

- Patents 5,686,104 (May 11, 2015), 5,969,156 (Jan 8, 2017), and 6,126,971 (Jul 19, 2013)

June 18, 2008: two parties settled

- Ranbaxy will have a license to sell the generic drug in US effective November 30, 2011



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Common ownership is common

- Bristol-Myers Squibb (brand) vs. Mylan (generic), 2013Q1

Top 20 Generic Shareholders	Generic Shares	Brand Shares
Vanguard	7.04%	4.61%
Paulson & Co. Inc.	4.72%	0.00%
BlackRock	5.03%	4.50%
State Street	4.35%	4.06%
Bank of America	3.91%	1.09%
Goldman Sachs	2.72%	0.46%
Fidelity	0.89%	0.40%
Wellington Management	3.67%	2.46%
Jennison Associates	1.15%	0.94%
Mellon Bank	1.79%	1.55%
Nordea Investment Management	1.65%	0.02%
Sectoral Asset Management	1.27%	0.00%
JPMorgan Chase	1.15%	1.15%
Northern Trust	1.39%	1.70%
MSDW	0.86%	1.12%
Janus Capital Management	2.40%	0.19%
Amvescap	1.22%	1.11%
College Retire Equities	1.22%	0.52%
BlackRock Advisors	0.52%	0.82%
Investeco Asset Management	1.25%	0.00%

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- The Paragraph Four Report® at Parry Ashford Inc.
- Entry date, whether and when brand suits, litigation date, generic/brand firms, drug name, active ingredient, formulation, patents at issue, court of district, lawyer/judge names, law firms, litigation outcome
- Cases that were "active" as of November 1, 2003

Institutional shareholdings

- Thomson-Reuters Spectrum dataset on 13F filings
- Voting and non-voting shares

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A Snapshot

Arthrotec® (diclofenac and misoprostol) Delayed-release Tablets

Company PFIZER

Date of First Filing November 28, 2008 (75mg/0.2mg) and June 29, 2009 (50mg/0.2mg)

Paragraph IV Applicant: Teva Pharmaceuticals (Barr)

Case Name: PFIZER v. TEVA PHARMACEUTICALS

Court/Case #: New York Southern District Court (nysdc) 1:2009cv03965

Date Filed: 4/21/2009

Judge: Sullivan

Product Strength: 75 mg/0.2 mg and 50mg/0.2mg

Litigated Patents (expiration): 5,601,843 (2/11/2014)




Non-Litigated Patents (expiration): 5,698,225 (5/3/2010)


Plaintiff Lawyer/Firm: Thom Beck/Sidley Austin

Defendant Lawyer/Firm: David Hashmall/Goodwin Procter

Related Case: None. Amended Complaint adds 50mg/0.2mg strength

Status: The parties entered settlement agreement and consent judgment entered 1/22/10.

 [Complaint](#)  [Amended Complaint](#)  [Answer](#)

 [Consent Judgment](#)

Product Links from FDA and USPTO

[Orange Book Patent & Exclusivity Data](#)

['843 Patent](#)

['225 Patent](#)

Descriptive Statistics

- Sample unit: each distinct Paragraph IV application at the date-tradename-formulation level

Brand name drugs	377
Brand incumbents	120
Generic entrants	133
Formulations of brand name drugs	451
Challenges	1,339

- Distribution by listing status

	N	Percentage
Generic public & brand public	293	21.9%
Generic public & brand private	252	18.8%
Generic private & brand public	310	23.2%
Generic private & brand private	484	36.1%
Total	1,339	100.0%

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Litigation Outcomes across Federal District Courts

Federal District Court	# of challenge	# of patent settlement	brand win	brand lose	unknown	settlement%	# of patents/challenge	
California Central	16	39	35	0	4	0	89.7%	2.44
California Northern	12	50	47	1	2	0	94.0%	4.17
Colorado	2	9	9	0	0	0	100.0%	4.50
Delaware	379	1,069	805	121	113	30	75.3%	2.82
District of Columbia	4	4	4	0	0	0	100.0%	1.00
Florida Middle	2	2	2	0	0	0	100.0%	1.00
Florida Southern	8	15	10	4	1	0	66.7%	1.88
Georgia Northern	7	12	8	3	1	0	66.7%	1.71
Illinois Northern	55	138	114	12	12	0	82.6%	2.51
Indiana Southern	44	111	81	27	3	0	73.0%	2.52
Maryland	29	52	51	0	1	0	98.1%	1.79
Massachusetts	14	25	25	0	0	0	100.0%	1.79
Michigan Eastern	9	24	18	0	6	0	75.0%	2.67
Michigan Western	1	2	2	0	0	0	100.0%	2.00
Minnesota	5	11	9	0	2	0	81.8%	2.20
Nevada	8	45	20	23	2	0	44.4%	5.63
New Jersey	432	1,097	862	114	113	8	78.6%	2.54
New York Eastern	7	10	7	0	3	0	70.0%	1.43
New York Southern	118	395	356	28	11	0	90.1%	3.35
North Carolina Eastern	11	19	15	4	0	0	78.9%	1.73
North Carolina Middle	4	13	9	4	0	0	69.2%	3.25
Ohio Northern	1	12	0	2	10	0	0.0%	12.00
Ohio Southern	2	9	9	0	0	0	100.0%	4.50
Pennsylvania Eastern	18	55	38	0	17	0	69.1%	3.06
Pennsylvania Western	1	4	0	4	0	0	0.0%	4.00
Pennsylvania Middle	1	3	3	0	0	0	100.0%	3.00
Puerto Rico	1	3	3	0	0	0	100.0%	3.00
Texas Eastern	5	13	8	3	2	0	61.5%	2.60
Texas Northern	7	14	14	0	0	0	100.0%	2.00
Vermont	1	1	0	1	0	0	0.0%	1.00
Virginia Eastern	12	21	11	1	9	0	52.4%	1.75
West Virginia Northern	1	4	0	4	0	0	0.0%	4.00
West Virginia	2	2	0	0	2	0	0.0%	1.00
West Virginia North	9	19	16	1	2	0	84.2%	2.11
N/A	6	9	8	0	0	1	88.9%	1.50
Brand does not suit	105	286						
Total	1,339	3,597	2,599	357	316	39	72.3%	2.69

Institutional Cross-holdings

- Both brand and generic are publically listed firms

	Mean	SD	Min	p1	p25	p50	p75	p99	Max	N
Generic shares held by top 10 generic shareholders	24.7%	14.7%	0.0%	0.0%	9.1%	24.6%	36.7%	54.0%	54.5%	291
Generic shares held by top 15 generic shareholders	29.3%	17.5%	0.0%	0.0%	10.9%	29.6%	44.1%	63.6%	64.1%	291
Generic shares held by top 20 generic shareholders	32.5%	19.6%	0.0%	0.0%	11.5%	33.0%	48.9%	70.1%	72.1%	291
Generic shares held by top 25 generic shareholders	35.0%	21.1%	0.0%	0.0%	11.8%	35.7%	52.7%	75.5%	78.0%	291
Generic shares held by top 30 generic shareholders	37.0%	22.4%	0.0%	0.0%	12.0%	38.2%	55.6%	81.1%	83.2%	291
Brand shares held by top 10 generic shareholders	9.5%	7.8%	0.0%	0.0%	2.9%	8.1%	15.1%	30.1%	41.9%	291
Brand shares held by top 15 generic shareholders	12.4%	9.0%	0.0%	0.0%	4.9%	12.4%	18.8%	39.1%	49.1%	291
Brand shares held by top 20 generic shareholders	14.3%	9.9%	0.0%	0.0%	5.2%	14.5%	21.4%	48.7%	50.4%	291
Brand shares held by top 25 generic shareholders	16.1%	11.0%	0.0%	0.1%	6.1%	16.9%	23.3%	50.4%	53.8%	291
Brand shares held by top 30 generic shareholders	17.4%	11.7%	0.0%	0.1%	6.5%	18.8%	25.3%	51.3%	55.6%	291
Top 10 generic shareholders' weight on brand	29.1%	20.4%	0.0%	0.0%	12.9%	29.1%	40.4%	86.1%	99.9%	291
Top 15 generic shareholders' weight on brand	32.3%	21.3%	0.0%	0.2%	16.2%	30.5%	45.6%	85.0%	99.9%	291
Top 20 generic shareholders' weight on brand	33.3%	21.7%	0.0%	0.3%	18.5%	31.5%	45.8%	85.6%	99.9%	291
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Plan for the Talk

- Empirical Strategy
- Institutional Setting
- Data/Sample
- Cross-holdings and Settlement
- Anticompetitive Effects of Settlement
- Delayed Generic Entries

Empirical Specification

$$\text{Settlement}_{i,j,s} = \alpha + \beta \times \text{Top } N \text{ generic shareholders' weight on brand}_{j,s-1} + X'_{t-1} \times \gamma_1 + \gamma_2 \times \text{Group} + \phi_j \times \text{Group} + \phi_l + \phi_k + \phi_t + \epsilon_{i,j,s}$$

where

- *Settlement*: dummy variable indicating whether two parties settled
- *X*:
 - ▶ listing status: generic private & brand public, generic public & brand private, both private
 - ▶ top drug sales, dummy indicating non-top drugs, group entry
- $\phi_j, \phi_l, \phi_k, \phi_t$: generic firm, brand firm, court, and year fixed effects

Most restrictive specification uses within-trade-name variation!

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	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Top 10 generic shareholders' weight on brand	0.151*					0.146*				
	(0.080)					(0.085)				
Top 15 generic shareholders' weight on brand		0.186**					0.191**			
		(0.082)					(0.088)			
Top 20 generic shareholders' weight on brand			0.136					0.188**		
			(0.100)					(0.079)		
Top 25 generic shareholders' weight on brand				0.164*					0.196**	
				(0.095)					(0.075)	
Top 30 generic shareholders' weight on brand					0.191**					0.215***
					(0.087)					(0.075)
Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Public status	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
District court FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Generic Firm FE	Yes	Yes	Yes	Yes	Yes					
Generic Firm FE × Group	Yes	Yes	Yes	Yes	Yes					
Brand firm FE	Yes	Yes	Yes	Yes	Yes					
Trade name FE						Yes	Yes	Yes	Yes	Yes
<i>N</i>	1,201	1,201	1,201	1,201	1,201	1,202	1,202	1,202	1,202	1,202
<i>adj. R</i> ²	0.29	0.29	0.29	0.29	0.29	0.45	0.45	0.45	0.45	0.45

2003 Mutual Fund Scandal

Mutual fund trading scandal of September 2003: Janus, Columbia Management Group, Franklin Templeton...

- Outflows of implicated fund families during 2003Q3-2006Q4
- Exogenous variation across brand-generic pairs as of 2003Q3
- Instrument

► $Brand\ Scandal=1$ if $\frac{\sum_{k=1}^N \alpha_{Scandal, b}^{k, 2003Q3}}{\sum_{k=1}^N \alpha_b^{k, 2003Q3}} > 10\%$

- Assumption 1: un-related to future generic entries
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Plan for the Talk

- Empirical Strategy
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Brand Incumbent's Return around Settlement

Anticompetitive effect

- $\mathbb{E}(\text{drug life} \mid \text{settlement}) > \mathbb{E}(\text{drug life} \mid \text{go to trial})$

$$CAR(-3, +3)_{i,j,s} = \alpha + \beta \times \text{Top } N \text{ generic shareholders' weight on brand}_{j,s-1} + X'_{j,s-1} \times \gamma + \phi_h + \phi_k + \phi_t + \epsilon_{i,j,s}.$$

Assumption

- Paragraph IV litigations are in the form public hearings
- Random measure errors during private hearings

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	Index funds					IV Estimation				
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Top 10 generic shareholders' weight on brand	0.021*** (0.007)					0.098* (0.054)				
Top 15 generic shareholders' weight on brand		0.025*** (0.006)					0.090* (0.050)			
Top 20 generic shareholders' weight on brand			0.025*** (0.007)					0.085* (0.048)		
Top 25 generic shareholders' weight on brand				0.028*** (0.007)					0.083* (0.046)	
Top 30 generic shareholders' weight on brand					0.029*** (0.006)					0.081* (0.045)
Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
District court FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trade name FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
N	490	490	490	490	490	429	429	429	429	429
adj. R ²	0.15	0.16	0.16	0.16	0.16					

Plan for the Talk

- Empirical Strategy
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- 180 Day Marketing Exclusivity

180 Day Marketing Exclusivity

First generic challenger **successfully defending** a suit

- will be granted with the 180 day marketing exclusivity
- settlements with the first can prevent/delay all entries

180 Day Marketing Exclusivity

$$\text{Marketing5}_{i,j,s} = \alpha + \beta_1 \times \text{Top N Weight}_{j,s-1} + \beta_2 \times \text{Top N Weight}_{j,s-1} \times \text{Excl} + \beta_3 \times \text{Excl} + X'_{j,t-1} \times \gamma + \phi_h + \phi_k + \phi_t + \epsilon_{i,j,s}$$

where

- *Marketing 5*: whether a generic drug is marketed within five years after the two parties settled
- *Excl*: whether a generic manufacturer is granted with the 180 day exclusivity

Most restrictive specification uses within-trade-name variation!

180 Day Marketing Exclusivity

	Index Funds					IV Estimation				
	(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
Top 10 generic shareholders' weight on brand	-0.205					-0.071				
	(0.328)					(0.217)				
Top 10 generic shareholders' weight on brand × Excl	-0.614***					-1.056				
	(0.195)					(0.793)				
Top 15 generic shareholders' weight on brand	-0.236					-0.065				
	(0.332)					(0.199)				
Top 15 generic shareholders' weight on brand × Excl	-0.597***					-1.079				
	(0.208)					(0.807)				
Top 20 generic shareholders' weight on brand			-0.260					-0.062		
			(0.317)					(0.189)		
Top 20 generic shareholders' weight on brand × Excl			-0.583**					-1.079		
			(0.212)					(0.806)		
Top 25 generic shareholders' weight on brand			-0.282					-0.060		
			(0.312)					(0.185)		
Top 25 generic shareholders' weight on brand × Excl			-0.558***					-1.061		
			(0.197)					(0.791)		
Top 30 generic shareholders' weight on brand				-0.290					-0.059	
				(0.288)					(0.182)	
Top 30 generic shareholders' weight on brand × Excl				-0.515***					-1.003	
				(0.185)					(0.749)	
Excl	0.295*	0.294*	0.293*	0.293*	0.294*	0.300**	0.300**	0.300**	0.300**	0.300**
	(0.159)	(0.160)	(0.160)	(0.160)	(0.161)	(0.122)	(0.123)	(0.123)	(0.123)	(0.123)
Controls	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Year FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Court FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Trade Name FE	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
N	629	629	629	629	629	513	513	513	513	513
adj. R ²	0.20	0.20	0.20	0.20	0.20					

Concluding Remarks

Hidden cost of portfolio diversification and good governance

- Fewer product market entries
- Loss of consumer welfare

Policy implication

- Section 7 of the Clayton Act
 - ▶ Exemption for stock acquisitions "solely for investment"
- US Antitrust authorities and European Commission

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