

Common Ownership and Market Entry

Evidence from the Pharmaceutical Industry

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Common ownership between brand and generic - example

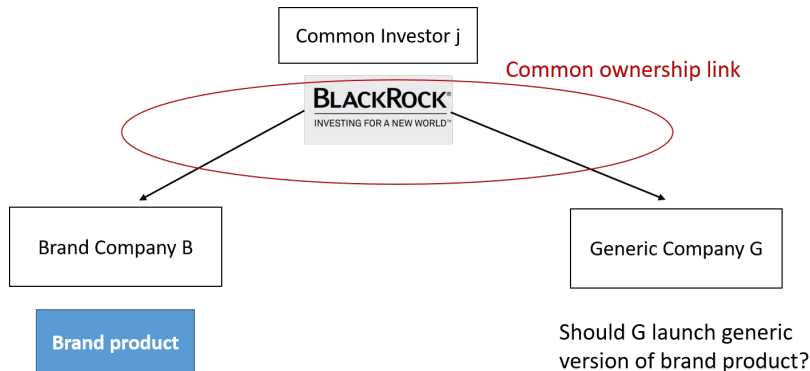
Table 1: Top 5 Largest Investors (2013)

Brand Johnson & Johnson		Generic Mylan	
State Street Global	6%	Vanguard Group	7%
BlackRock	6%	BlackRock	6%
Vanguard Group	5%	State Street Global	4%
Royal Bank of Canada	2%	Wellington Mgmt.	4%
Wellington Mgmt.	2%	John Paulson	4%

Source: Thomson Global Ownership Database

Research question

How does **common ownership** between a potential generic entrant and the brand (incumbent) influence the **generic's market entry decision**?



Investors discuss strategy with pharma companies

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Mutual Fund Industry to Drugmakers: Stand Up and Defend Yourself

by Caroline Chen

Updated on May 11, 2016, 4:37 pm

Published on May 9, 2016, 11:04 pm



In a sign of how U.S. political pressure to rein in drug pricing is weighing on pharmaceutical companies and their investors, a group of major funds called an unusual meeting with top biotech and pharma lobbyists, urging them to do a better job defending their industry.

The conclave occurred in March in a conference room at a Boston hotel. There, fund representatives, including those from [Fidelity Investments](#), [T. Rowe Price Group Inc.](#) and [Wellington Management Co.](#), exhorted drug industry executives and lobbyists to do a better job defending their pricing by educating the public about the value of their

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Entry in pharmaceutical markets

- ▶ **Market entry** represents an important strategic decision
- ▶ Particularly in the pharma industry, entry by a generic firm after regulatory protection has dramatic effects
 - ▶ Brands face revenue **declines of up to 90%** (Bransetter et al., 2016)
- ▶ Gains from deterring entry much higher than losses of not entering for generic companies (Jacobo-Rubio et al., 2017):
 - ▶ Brand firms' value deterring entry, on average, at about **\$4.6 billion**
 - ▶ Generic companies value the right to enter at about **\$236.8 million**

Theoretical framework

- ▶ Consider case of one potential generic entrant first. Assume entry
 - ▶ increases the market profits of generic G , from zero to $\pi_G > 0$, but
 - ▶ reduces profits of the brand B : $\Delta\pi_B \equiv \pi_B^D - \pi_B^M < 0$
 - ▶ joint profits decrease with entry as $\pi_G < |\Delta\pi_B|$
- ▶ Denote by δ weight decision-makers of G place on joint profits:

$$\Pi_G(\delta) \equiv (1 - \delta)\pi_G + \delta(\pi_G + \Delta\pi_B)$$

- ▶ Entry will only occur if these "net gains" are positive, i.e.

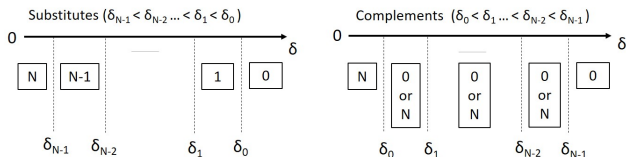
$$\Pi_G(\delta) = \pi_G + \delta\Delta\pi_B > 0.$$

- ▶ **Prediction 1: An increase in common ownership reduces entry incentives of the generic (as $\Delta\pi_B < 0$)**
- ▶ Holds if there are $N - 1$ other potential entrants simultaneously deciding whether to enter the market of same brand drug

Equilibrium number of entrants

- ▶ Assume N potential symmetric entrants, both in terms of common ownership with the brand (δ) and profits (π_G^k)
- ▶ Define $\delta_i \equiv \pi_G^i / \Delta \pi_B^i$ where π_G^i and $\Delta \pi_B^i$ are the generic entry profits and loss in brand profits when i other generics have entered

Figure 1: Number of entrants in equilibrium as a function of δ

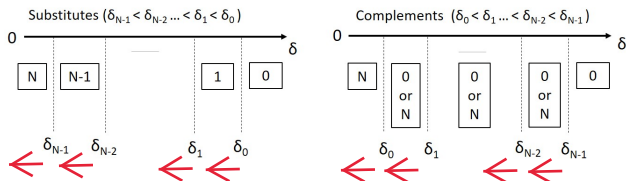


- ▶ **Prediction 2: The equilibrium number of entrants decreases as the level of common ownership increases**

Comparative statics with respect to market size

- Assume that in larger markets the losses of the brand are relatively larger than the gains of the generic, i.e., $\delta_i \equiv \pi_G^i / \Delta \pi_B^i$ decreases in market size

Figure 2: Number of entrants in equilibrium as a function of δ



Measuring common ownership

1. Shareholdings can be “perfect substitutes”: $\delta_S = \sum_{j=1}^M \frac{(\gamma_{jB} + \gamma_{jG})}{2}$

2. Shareholdings can be “perfect complements”: $\delta_C = \sum_{j=1}^M \min(\gamma_{jB}, \gamma_{jG})$

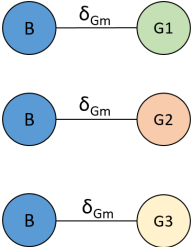
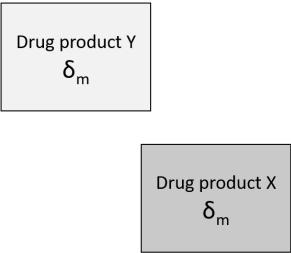
3. Weighted sum of financial interests: $\delta_L = \frac{\sum_i \gamma_{iB} \gamma_{iG}}{\sum_i \gamma_{iG}^2}$

where $j = 1, \dots, M$ are the investors that B and G have in common and i are *all* investors in either brand or generic or both. γ_{iB} is the size of the shareholding of investor i in brand (e.g. 5%) and γ_{iG} is size of shareholding of investor i in generic

Data

- ▶ Dataset merging
 1. **FDA Orange Book** of all approved drugs for the US
 2. **Thomson Reuters Global Ownership Database**
- ▶ Additional data from *drugs.com*, Drugs@FDA database and FDA list of authorized generics
- ▶ 451 prescription drug products (“entry opportunities”) that faced end of regulatory protection between 2004 and 2014
- ▶ Focus on early generic entrants (entry within 6 quarters after market becomes open for entry), who decide simultaneously
- ▶ Potential entrant set: firms that have launched a generic in at least one market in our sample with 6 quarters

Empirical implementation: Overview

	<u>Individual Entry</u>	<u>Market Outcomes</u>
		
Unit of observation	Brand drug product-potential generic entrant pair	Drug product market
Dependent var.	Entry decision of generic G	Total number of generic entrants
Measures of CO	Three pairwise measures: δ_S , δ_C , δ_L	Market average measures
Model	OLS and IV	Negative Binomial

Pairwise analysis

$$\Pr[Entry_{Gm} = 1] = \beta_0 + \beta\delta_{Gm} + \eta Z_m + \gamma X_{Gm} + A_m + \alpha_t + \epsilon_{Gm}$$

- ▶ Probability of entering specified as a function of generic and market characteristics (as in e.g. Scott Morton, 1999)
- ▶ $Entry_{Gm}$ takes 1 when generic G enters drug market m within six quarters after market becomes open for entry

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- ▶ Probability of entering specified as a function of generic and market characteristics (as in e.g. Scott Morton, 1999)
- ▶ $Entry_{Gm}$ takes 1 when generic G enters drug market m within six quarters after market becomes open for entry
- ▶ δ_{Gm} : measure of common ownership
- ▶ Z_m : market characteristics (e.g. brand sales)
- ▶ X_{Gm} : generic-market characteristics (e.g. prior experience)
- ▶ A_m : market fixed effects (therapeutic field, form, submission type)
- ▶ α_t : year of end of exclusivity

Instrumental variables

Endogeneity concern: investors may react to entry opportunities and adjust their portfolios

IV strategy with two instruments:

1. **Index membership:** No. periods that both firms in pair are in the BlackRock iShares U.S. Pharmaceutical ETF
 - ▶ Investors tracking the index will adjust shareholdings to reflect U.S. pharma index
 - ▶ Inclusion in the index should not be related to entry decisions

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2. **HQ location:** indicator variable taking value 1 if headquarters of both firms are in the same geographic region
 - ▶ If both brand and generic have their headquarters in the same region higher common ownership is expected (“home bias” of certain investors)
 - ▶ Generics should not be more/less likely to enter the markets of brand firms from the same region

Results: pairwise analysis

	OLS			IV		
	(1)	(2)	(3)	(4)	(5)	(6)
δ_S	-0.0121***			-0.0234**		
δ_C		-0.0422***			-0.0601**	
δ_L			-0.0166***			-0.0187**
Subsidiary (0/1)	-0.0411***	-0.0406***	-0.0411***	-0.0427***	-0.0412***	-0.0413***
Sales Rank (1-10) (0/1)	0.0219***	0.0219***	0.0218***	0.0221***	0.0220***	0.0218***
Sales Rank (11-50) (0/1)	0.0223***	0.0223***	0.0224***	0.0225***	0.0224***	0.0224***
Sales Rank (51-100) (0/1)	0.0177***	0.0178***	0.0177***	0.0178***	0.0179***	0.0177***
Authorized Generic (0/1)	0.000922	0.000928	0.000930	0.000870	0.000907	0.000924
Substitutes on Patent (ATC2)	-0.00445**	-0.00448**	-0.00444**	-0.00454**	-0.00453**	-0.00445**
Substitutes off Patent (ATC2)	-0.000814	-0.000788	-0.000827	-0.000762	-0.000753	-0.000821
Experience Route	0.00835***	0.00834***	0.00836***	0.00835***	0.00834***	0.00836***
Experience ATC2	0.0602***	0.0602***	0.0601***	0.0601***	0.0601***	0.0601***
Experience New Drug	0.00434*	0.00431**	0.00475**	0.00549**	0.00483**	0.00496**
Breadth (ATC2)	0.00325***	0.00333***	0.00329***	0.00343***	0.00345***	0.00332***
Generic region of origin	Yes	Yes	Yes	Yes	Yes	Yes
Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Constant	0.0296***	0.0293***	0.0292***	0.0299***	0.0293***	0.0292***
Observations	58,737	58,737	58,737	58,737	58,737	58,737
Drug Markets	451	451	451	451	451	451
R-squared	0.079	0.079	0.079			

Notes: Standard errors are robust. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.

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- ▶ Economic magnitude: one standard deviation increase in δ_S implies a **9% reduction** in the unconditional entry probability

Market-level analysis

- ▶ Count model for the total number of generic entrants in the market within 6-quarters after market opening
- ▶ Given dispersed numbers, apply a negative binomial estimator.
- ▶ Market-based average measure of δ_S including:
 - ▶ all potential generic entrants
 - ▶ top 50 most experienced at the drug form/route level
 - ▶ top 20 most experienced at the drug form/route level
- ▶ Market-level specification:

$$NumEntrants = \beta_0 + \beta Average\delta_{Sm} + \eta Z_m + \alpha_m + \epsilon_m \quad (1)$$

Results: market-level analysis

	All		Top 50		Top 20	
	(1)	(2)	(3)	(4)	(5)	(6)
	$\partial y / \partial x$		$\partial y / \partial x$		$\partial y / \partial x$	
Average δ_S	-2.479*	-6.479*	-1.968**	-5.149**	-1.515**	-3.962**
Sales top 100 (0/1)	0.615***	1.608***	0.620***	1.621***	0.621***	1.623***
Authorized Generic (0/1)	0.167	0.438	0.163	0.427	0.167	0.437
Substitutes on Patent (ATC2)	-0.221	-0.577	-0.219	-0.573	-0.222	-0.581
Substitutes off Patent (ATC2)	0.0786	0.205	0.0745	0.195	0.0701	0.183
Fixed Effects	Yes	Yes	Yes	Yes	Yes	Yes
Constant	0.970*		0.994*		1.010*	
Observations	451	451	451	451	451	451
R^2_{corr}	0.404		0.403		0.406	
R^2_{pseudo}	0.122		0.123		0.123	

Notes: Negative Binomial Regression. Standard errors in parentheses are robust. The dependent variable is total number of entrants within 6 quarters. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.

Results: market-size

VARIABLES	OLS		IV	
	(1) Largest 50%	(2) Smallest 50%	(3) Largest 50%	(4) Smallest 50%
δ_S	-0.0376*** (0.0104)	0.00232 (0.00575)	-0.0731*** (0.0282)	-0.00412 (0.0166)
Observations	25853	25751	25853	25751
R-squared	0.108	0.0445	0.0906	0.0381
Therapeutic field	Yes	Yes	Yes	Yes
Drug form	Yes	Yes	Yes	Yes
Submission type	Yes	Yes	Yes	Yes
Generic region of origin	Yes	Yes	Yes	Yes
Year end of exclusivity	Yes	Yes	Yes	Yes

Notes: Standard errors in parentheses. The dependent variable is total number of entrants within 6 quarters. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.

Summary of results

- ▶ This paper contributes to evidence that **common shareholders influence strategic decisions** of companies
- 1. Higher common ownership robustly linked to lower entry probabilities
- 2. Negative impact of common ownership is **strongest when common ownership levels are high**
- 3. The impact of complete common ownership is **smaller than the effect of being a subsidiary**
 - ▶ 1% decline vs. 4% decline *ceteris paribus*
- 4. Higher common ownership linked to **lower market entry**
- 5. Effects of common ownership on entry **only present in large markets**

Thank you for your attention.

Measuring common ownership

- ▶ Unclear exactly how to translate common shareholdings into δ (weight that the generic firm places on joint profits)
- ▶ We posit that
 - ▶ shareholdings in brand provide investors with *incentives* to steer decisions towards joint profits whereas
 - ▶ shareholdings in the generic provide *ability* to influence such decisions
- ▶ We use several measures of common ownership, which differ in the way incentives and ability to influence decisions are taken into account

Production function approach

- ▶ Transforms each common investor j 's shareholdings in the two firms $(\gamma_{jG}, \gamma_{jB})$ (inputs) into a "joint-profit-steering" index (output)
- ▶ Assuming perfect coordination among common investors,

$$\delta = \sum_j f(\gamma_{jG}, \gamma_{jB}), \quad (2)$$

- ▶ Increasing in γ_{jB} (incentives) and γ_{jG} (ability) with some degree of complementarity between the two
- ▶ Two extreme production function examples:
 - ▶ "perfect substitutes," i.e., $f(\gamma_{jG}, \gamma_{jB}) = (\gamma_{jG} + \gamma_{jB})/2$
 - ▶ "perfect complements," i.e., $f(\gamma_{jG}, \gamma_{jB}) = \min\{\gamma_{jG}, \gamma_{jB}\}$

Weighted sum of interests approach

- ▶ Generic firm maximizes a weighted sum of the interests of all investors in the generic firm (Salop and O'Brien, 2000), where
 - ▶ (i) interests of an investor are given by her holdings in two firms and
 - ▶ (ii) weights are given by investor's degree of control of generic firm,

$$\sum_i \gamma_{iG} [\gamma_{iG} \pi_G + \gamma_{iB} \pi_B]$$

- ▶ This is equivalent to maximizing

$$\pi_G + \frac{\sum_i \gamma_{iG} \gamma_{iB}}{\sum_i \gamma_{iG}^2} \pi_B$$

and thus, the measure (often called “lambda”)

$$\delta_L \equiv \frac{\sum_i \gamma_{iG} \gamma_{iB}}{\sum_i \gamma_{iG}^2}$$

Appendix

Data

Variable	Obs.	Mean	Std. Dev.	Min	Max
Entry (0/1)	58737	0.02	0.14	0	1
δ_S	58737	0.074	0.15	0	0.868
δ_C	58737	0.021	0.051	0	0.366
δ_L	58737	0.062	0.16	0	1.365
Cross Ownership (0/1)	58737	0.002	0.046	0	1
Sales Top 100 (0/1)	58737	0.158	0.365	0	1
Authorized Generic (0/1)	58737	0.26	0.439	0	1
Substitutes on Patent (ATC2) $\div 10$	58737	2.325	1.669	0	7.3
Substitutes off Patent (ATC2) $\div 10$	58737	1.6	1.31	0	6.1
Experience Route $\div 10$	58737	1.305	3.086	0	29.9
Experience ATC2 $\div 10$	58737	0.07	0.223	0	3.2
Experience New Drug $\div 10$	58737	0.179	0.424	0	2.8
Breadth (ATC2) $\div 10$	58737	1.135	1.204	0	6.1

Table 2: Pairwise Analysis: Summary Statistics

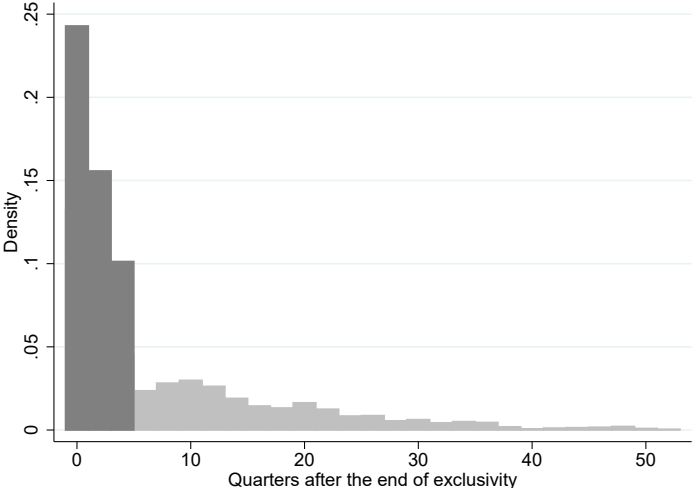
Data

Variable	Obs.	Mean	Std. Dev.	Min	Max
Number of entrants	451	2.608	3.249	0	18
δ_S - all	451	0.074	0.044	0	0.176
δ_S - top 50	451	0.112	0.069	0	0.307
δ_S - top 20	451	0.138	0.085	0	0.325

Table 3: Market-level Analysis: Summary Statistics

Data

Figure 3: Entry patterns



Instrumental variables

Figure 4: iShares U.S. Pharmaceutical (IHE) ETF

iShares U.S. Pharmaceuticals ETF

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Overview

Performance

Key Facts

Characteristics

Fees

Portfolio

Literature

Top 10

All

as of

Nov 29, 2013



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Ticker	Name	Sector	Weight (%)	Notional Value
JNJ	JOHNSON & JOHNSON	Pharmaceuticals	10.43	-
PFE	PFIZER INC	Pharmaceuticals	9.59	-
MRK	MERCK & CO INC	Pharmaceuticals	7.85	-
BMY	BRISTOL MYERS SQUIBB	Pharmaceuticals	6.84	-
ABT	ABBOTT LABORATORIES	Pharmaceuticals	5.59	-
A60	ACTAVIS INC	Pharmaceuticals	5.06	-
LLY	ELI LILLY	Pharmaceuticals	4.76	-
AG4	ALLERGAN	Pharmaceuticals	4.19	-
MYL	MYLAN INC	Pharmaceuticals	3.38	-
PRGO	PERRIGO COMPANY	Pharmaceuticals	3.32	-

Identification

Southern Asia		Eastern Asia		Northern Europe	
Life Insurance of India	12	Bank of Tokyo-Mitsubishi	7	BlackRock	6
Citigroup	7	Nomura Holdings	6	Invesco	5
La Caixa	7	Nippon Life Insurance	6	Aviva	5
fil investment management	7	Sumitomo Life Insurance	4	NBIM	5
HDFC Asset Mgmt	6	Nikko Asset Mgmt	4	HarbourVest Partners	5
Western Europe		Northern America			
BlackRock	10	BlackRock	65		
Fidelity Investments	9	Vanguard Group	59		
NBIM	8	State Street Global	57		
HarbourVest Partners	6	Northern Trust Global	45		
Franklin Templeton	6	Fidelity Investments	42		

Table 4: Top common owners in each region for pharmaceutical firms and their number of blockholdings >1% (2009)

Results

	(1)	(2)	(3)
	δ_S	δ_C	δ_L
Index Periods	0.0527***	0.0207***	0.0652***
Same Region	0.0103***	0.00635***	0.00614***
Constant	0.0776***	0.0197***	0.0547***
Observations	58,737	58,737	58,737
Drug markets	451	451	451
R-squared	0.285	0.298	0.293
Fixed Effects	Yes	Yes	Yes
F-Test	156.7	110.7	115
F-Test (p-val)	0	0	0
Weak Instrument	2289	2253	2215
Endogeneity test (p-val)	0.276	0.445	0.757

Notes: Standard errors in parentheses are robust. For simplicity only the coefficients associated with the excluded instruments are reported. *** $p < 0.01$, ** $p < 0.05$, * $p < 0.1$.

Table 5: First Stage

Other robustness checks

- ▶ Different potential entrant sets
 - ▶ Potential entrants with experience in drug form/route
 - ▶ Potential entrants with experience in therapeutic field
- ▶ Measuring common ownership at different points in time
 - ▶ 2 years before market is open for entry
 - ▶ 0 years before market is open for entry
- ▶ Different entry windows
 - ▶ Entry within 1 year after market becomes open
 - ▶ Entry within 2 years after market becomes open
- ▶ Additional measures of common ownership
 - ▶ δ_M (Gilje et al., 2018); δ_G (Gilje et al., 2018); δ_H (Harford et al., 2011)
- ▶ Different econometric specifications
 - ▶ Logit model
 - ▶ Probit model