Entry and pricing with fighting brands: Evidence from the pharmaceutical industry

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Industry

Prescription drugs in US can be:

1. Branded drugs: New molecules, protected by market exclusivities (e.g. patents).
2. Generic drugs: Bioequivalent to the branded drug.

After loss of market exclusivity (LOE) of branded drug:

- Generics enter.
- Brand drug manufacturer often responds by releasing an "Authorized Generic" (AG).
- AGs are chemically identical to branded drug but without brand label attached.

Entry and pricing

What rationalizes AG release? Price discrimination.

- Expensive branded drug $\Longrightarrow$ high brand-valuation + low price-sensitive consumers.
- Cheap AG and generics $\Longrightarrow$ low brand-valuation + high price-sensitive consumers.
- Commonly known as fighting brand strategy.

Structural model

Goal: Study economic factors and policies that affect AG and generic entry decisions.

This paper:

- Data: National data on sales and revenue for US (2004-2016) by drug.
- Stylized structural model: Demand, pricing and entry of generics and AG after LOE.

Structural model

Data: Sales and revenue data for prescription drugs at US-quarter level.

- Study *aggregate* industry dynamics like average price and entry decision in US.
- Cannot look at finer variation at insurance-plan level.
- Demand side = joint purchase decision by pharmaceutical intermediaries and consumers.
- Stylized model to highlight key economic factors.

Findings

1. Demand estimation: significant heterogeneity in price sensitivity and brand valuation; AG premium present.
2. Counterfactuals:
   - Not releasing AG is rationalized by economic cost differential between AG and generics.
   - Faster generic approval rate $\implies$ greater generic entry, lower likelihood of AG being released, and lower overall prices.
   - AG ban $\implies$ higher overall market prices.

Motivation

Why is this useful?

- Contribute to nascent empirical IO literature on fighting brands.
- High drug prices mitigated by post-LOE competition.
- Contribute to papers on Authorized Generics.
  - First to build structural model of entry and competition between generics and AG.
- Policy discussion surrounding banning AG.

Key institutional details

1. Generic manufacturer needs FDA approval before launching product.

   Generic approval time is:

   - Lengthy (Mean time $\approx$ 40 months).
   - Stochastic.

2. AGs can be introduced anytime and without approval.

Example: pricing after LOE Example: market share after LOE

Data

Data from IQVIA for 2004-2016 on the US.

- Quarterly sales of each drug in US
- Revenue of each drug (gives us average price)
- Formulation of product (oral, injectable, etc.)
- Active ingredients/molecule composition

Data on Authorized Generics and Paragraph IV Exclusivity hand-collected.

Data

We define markets at the molecule-formulation (molform) level.

After data-cleaning:

- Prescription drugs.
- 246 molforms.
- 110 molforms see AG released.
- 60% of AGs released within one quarter of first generic entrant. Distribution of AG release timing
- Number of generics in molform range from 1-20, with a median of 4.

Each molform has one brand and can have at most one AG.

Structural model: Demand

Agent i looking to purchase a molecule-formulation makes a discrete choice from set of products (brand, AG, any generic).

$$u_{ijt} = \gamma_{m(j)} + \alpha_i ln\, p_{jt} + \beta_i^{(1)} \cdot \text{non-brand}_j + \beta^{(2)} \cdot AG_j + \beta^{(3)} brand_j \cdot \text{time-since-loe} + \xi_{jt} + \epsilon_{ijt}$$

where $\alpha_i \sim \mathcal{N}(\alpha, \sigma_\alpha^2)$, and $\beta_i^{(1)} \sim \mathcal{N}(\beta^{(1)}, \sigma_1^2)$

Estimation:

- BLP (1995).
- Roughly speaking, regress product's US market share on covariates.

Structural model: Supply

A model with two stages:

1. First stage: Generic firms decide whether to enter a molform.
    - Static entry game.
2. Second stage: LOE happens, then every period:
    - Random number of generics gain FDA approval.
    - Brand manufacturer decides whether to release AG.
    - Price competition between brand, generics and AG.

Supply: Second stage

Branded drug manufacturer's per-period payoff:

$$\pi^b(s_t) = [P_t^b - MC^b]s_b(s_t)M_t - \phi^b + \mathbf{1}(AG_t = 1)\left[[P_t^{AG} - MC^{AG}]s_{AG}(s_t)M_t - \phi^{AG}\right]$$

Generic firm l's per-period payoff:

$$\pi^g(s_{l,t}) = (P_t^g - MC^g)s_g(s_{l,t})M_t - \phi^g$$

where ϕ^j = operating cost of entity j

Supply: Second stage

Pricing:

- Nash-Bertrand pricing between generics and AGs.
- Price fixed at observed level for brand.

n_e^* = no. of generics that applied for FDA approval.

- Determined in First stage.

At $t = 0$, LOE happens.

For every $t \leq T$:

- Random number of n_e^* generics gain FDA approval.
- AG enters (irreversible) or stays out.

Supply: Second stage

Value function for branded drug manufacturer:

$$V^b(s_t, \varepsilon_t) = \max_{AG_{t+1} \in \{0,1\}} \pi^b(s_t) - \mathbf{1}(AG_t = 0, AG_{t+1} = 1)\kappa^{AG} + \beta E[V^b(s_{t+1}, \varepsilon_{t+1})|s_t, \varepsilon_t] + \varepsilon_t(AG_{t+1})$$

Value function for generic l:

$$V^g(s_{l,t}) = \pi^g(s_{l,t}) + \beta E[V^g(s_{l,t+1})|s_{l,t}]$$

Supply: Second stage

FDA approval rate modeled as binomial process.

Probability that k of the m unentered generics will gain FDA approval in time t:

$$P_e(k, m, t) = \binom{m}{k} \lambda(t)^k (1 - \lambda(t))^{m-k}$$

where $\lambda(t)$ is estimated from data.

Assumption: n_e^* is known to everyone in $t = 0$.

Supply: Second stage

After period T, market state is set at s_T.

The manufacturer receives this payoff for infinite periods:

$$V^b(s_T) = \sum_{\tau=T}^{\infty} \beta^\tau \pi^b(s_T)$$

Similarly, for generics the payoff is:

$$V^g(s_T) = \sum_{\tau=T}^{\infty} \beta^\tau \pi^g(s_T)$$

Supply: First stage

In the First Stage, generic manufacturers decide if they want to apply for FDA approval.

Assumptions:

- Generic firms are ex-ante identical.
- Do not receive private error draws for entering and staying out.
- Do not know their draws of ξ_{jt} conditional on entry.

Equilibrium generic entrants n_e^* determined by:

$$V^g(s_0, n_e^*) \geq \kappa^g > V^g(s_0, n_e^* + 1)$$

where κ^g is generic's entry cost.

Results from demand estimation

	Demand
ln(price)	-3.017
	(0.019)
Non-brand	-4.807
	(0.116)
AG	0.372
	(0.067)
Brand * time-since-LOE	-0.041
	(0.004)
RC: Non-brand	3.381
	(0.092)
RC: Price	0.240
	(0.034)

Table 1: Results of demand estimation

Supply

Cost parameters:

- Nash-Bertrand FOC gives marginal cost for each product.
- Remaining cost parameters calibrated:
    - Economic intuition should hold at different calibrated values.

Supply model solved by backward induction ($T = 32$).

Counterfactuals

We explore the following counterfactuals:

1. Rationalizing AG entry/non-entry.
2. Faster FDA approval rates.
3. Ban on AG.

Method:

1. Set up hypothetical molecule-formulation.
2. Solve model for a counterfactual.
3. Simulate model 3000 times.
4. Report average outcomes.

Counterfactuals

Data: 40% of molforms do not see AG entry. Why not?

AG non-entry rationalized by ϕ^{AG} being much larger than ϕ^{g}

Counterfactual results

Other possibilities may be ruled out by estimates and institutional details.

1. High cannibalization from brand.
2. High AG entry cost.
3. High AG marginal cost.

Counterfactuals

FDA approval rate (normalized)	Total generics	AG release fraction
0.75	3.0	1.0
1.0	4.0	1.0
2.0	5.0	1.0
4.0	5.0	1.0
6.0	5.0	1.0

AG price	Generic price	Per-Generic share	Brand share	AG share
2.97	2.85	22.37	4.13	28.76
2.88	2.79	18.13	3.67	23.82
2.82	2.75	15.25	3.38	20.39
2.81	2.74	15.23	3.42	20.43
2.8	2.74	15.22	3.43	20.45

Table 2: Market outcomes with changing FDA approval rates.

Counterfactuals

Cases	Total generics	AG release fraction	AG price	Generic price
Baseline	4	1.0	2.88	2.79
AG ban	5	0.0	0.0	2.91

Per-Generic share	Brand share	AG share
18.13	3.67	23.82
19.25	3.75	0.0

Table 3: Market outcomes with and without AG ban.

Conclusion

Goal: Study economic factors and policies that affect AG and generic entry decisions.

Findings:

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Example

Back

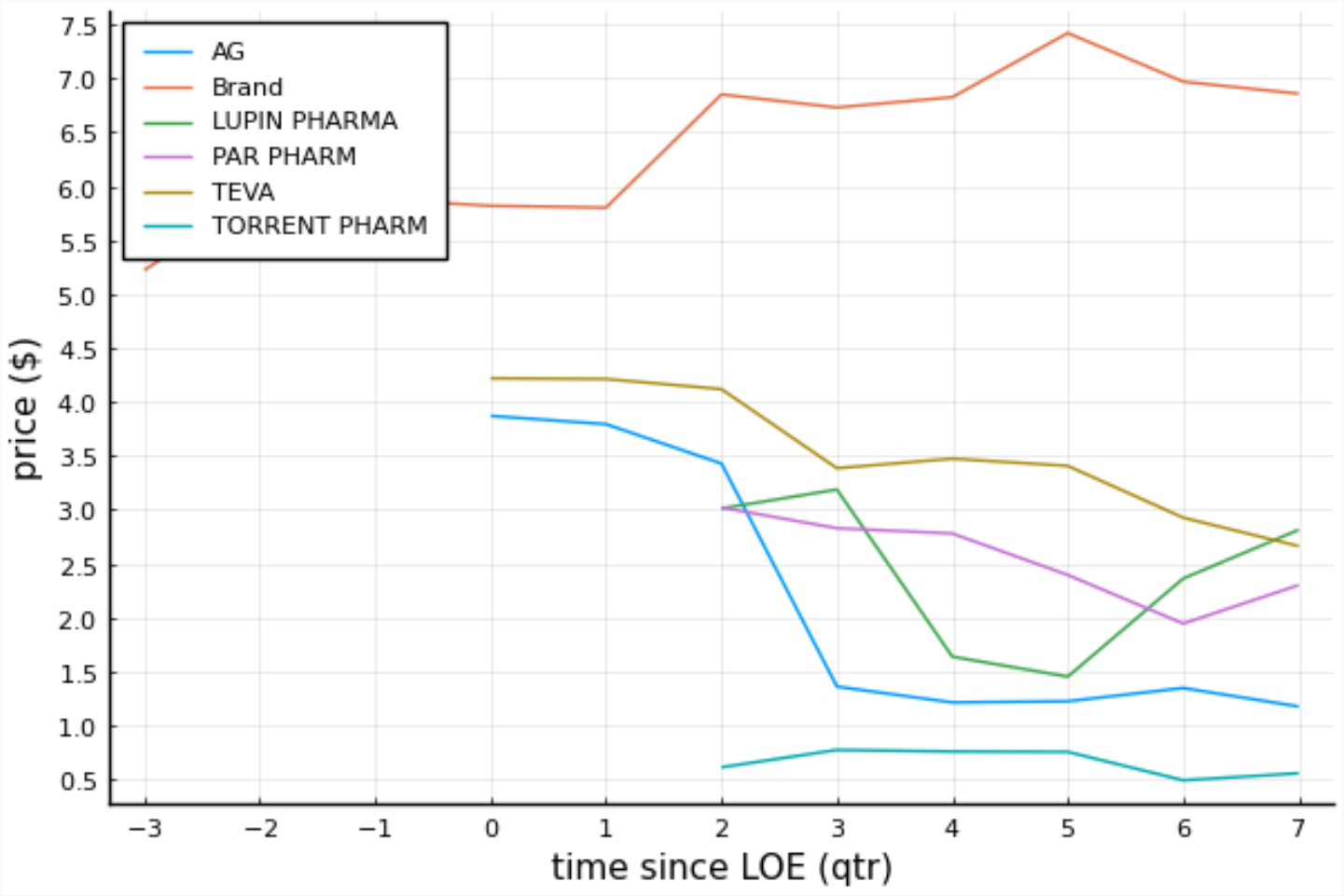

Figure 1: US-average prices for amlodipine-hydrochlorothiazide-valsartan (oral)

Example

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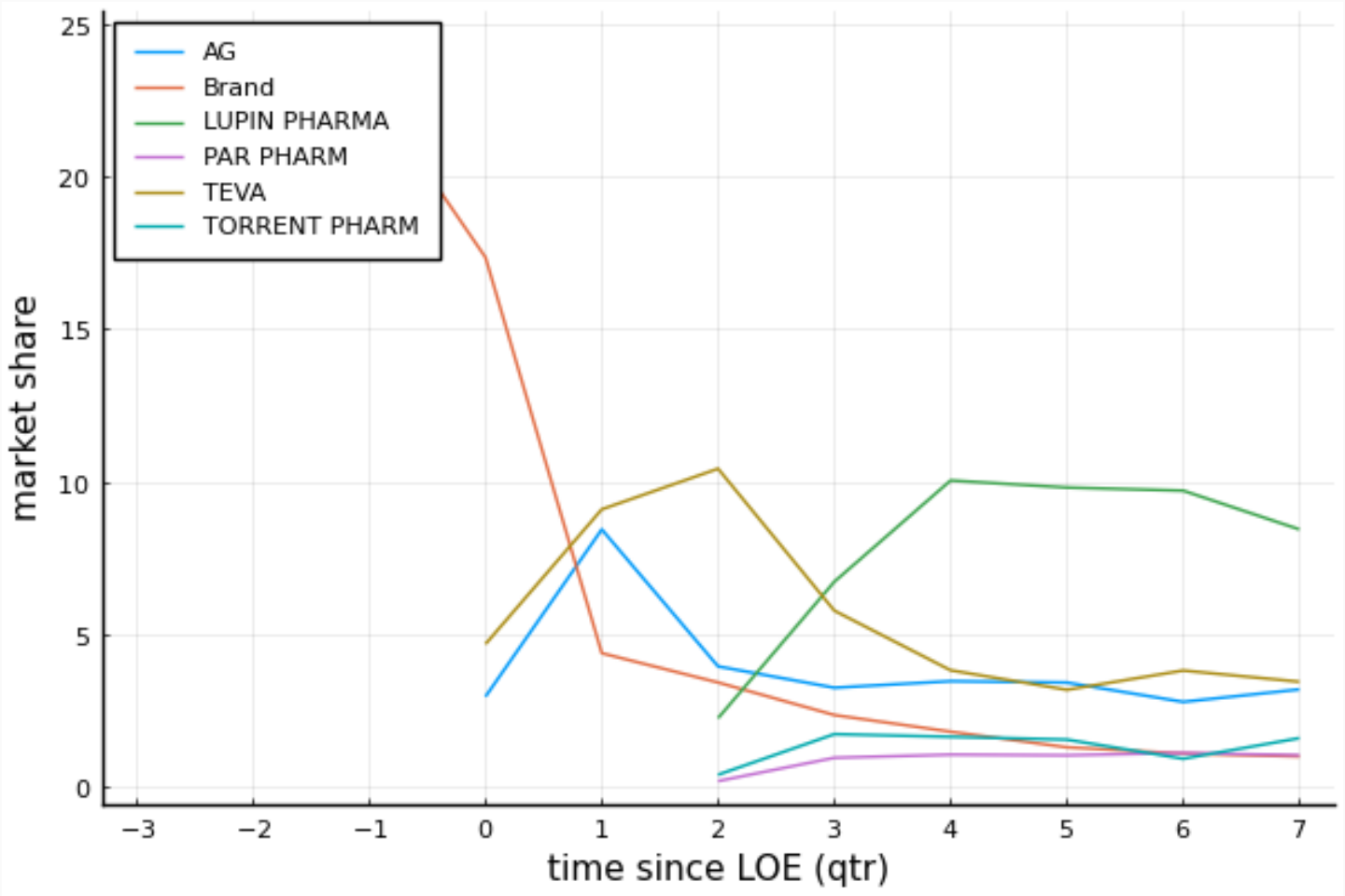

Figure 2: Market shares for amlodipine-hydrochlorothiazide-valsartan (oral)

Counterfactuals

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AG fixed cost	Total generics	AG release fraction	AG price	Generic price	Per-Generic share	Brand share	AG share
100000.0	4.0	1.0	2.88	2.79	18.13	3.67	23.82
110000.0	4.0	1.0	2.88	2.79	18.13	3.67	23.82
120000.0	4.0	1.0	2.88	2.79	18.13	3.67	23.82
130000.0	4.0	1.0	2.88	2.79	18.13	3.67	23.82
140000.0	5.0	0.01	2.85	2.91	15.68	3.06	18.56
150000.0	5.0	0.0	0.0	2.91	19.25	3.75	0.0
160000.0	5.0	0.0	0.0	2.91	19.25	3.75	0.0

Table 4: Market outcomes with changing operating cost of AG.

AG release

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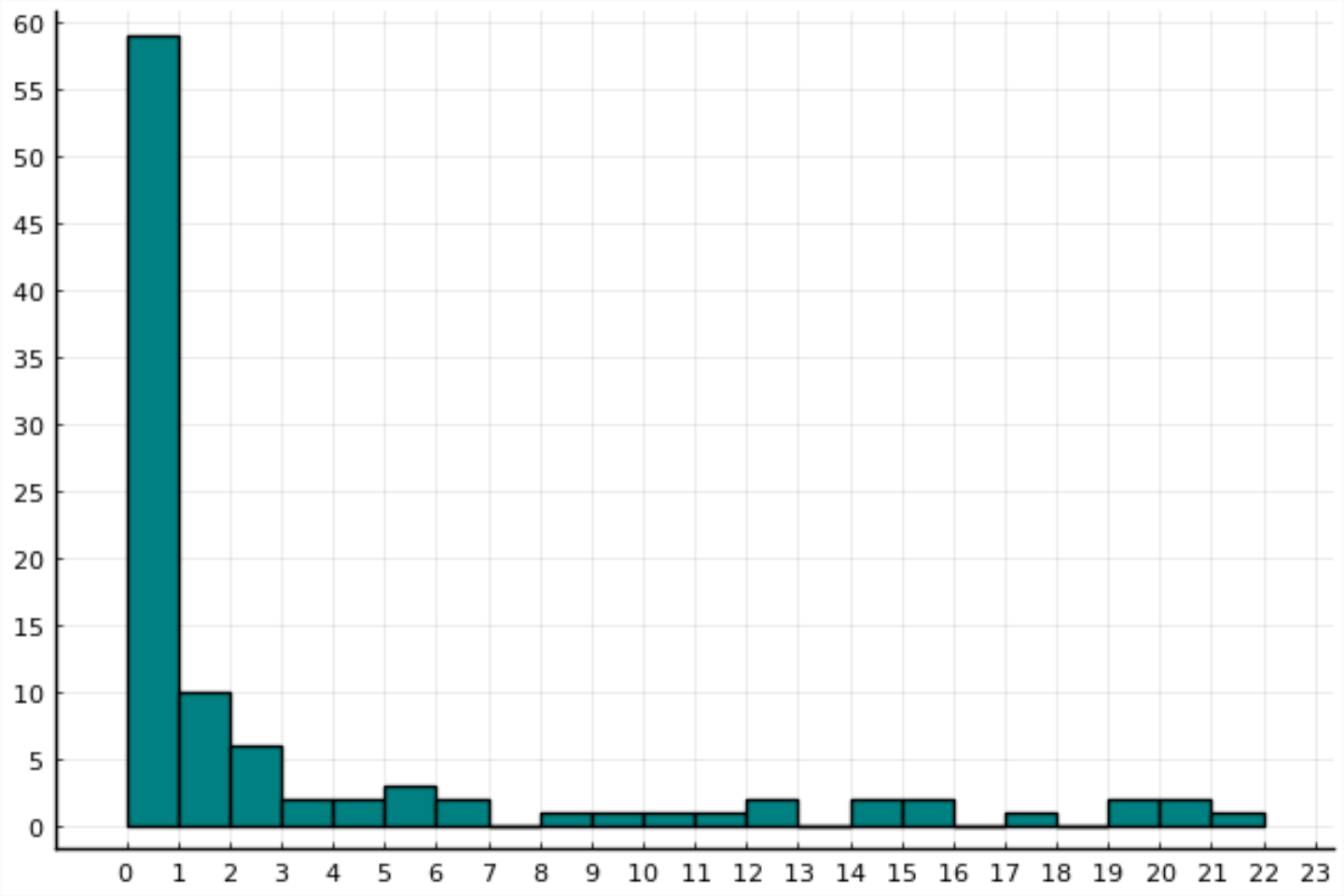

Figure 3: Time-difference between first generic entry and AG release period (in quarters).