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

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Industry

Pharmaceuticals in US can be broadly classified into two categories:

1. Branded drugs: New molecules, protected by patent for 15+ years. Enjoy monopoly in that market and charge monopoly price.
2. Generic drugs: Drugs which are bioequivalent to and cheaper than their branded counterparts.

Entry and pricing with AG

After patent expiration of original branded drug ("loss of exclusivity"), generics start entering.

- Brand drug manufacturer often responds by releasing a fighting brand, known as an "Authorized Generic" (AG).
- AGs are identical to the branded drug but without brand name attached.

Pricing patterns generally are:

- Brand drug price stays the same/rises.
- Generic and AG price stays low and falls over time.

Generic and AG entry

Generic approval time is lengthy and highly stochastic:

- Lengthy: Mean time is around 40 months.
- Stochastic: Hard to predict when approval will happen.

AGs can be introduced anytime and without approval, since they are riding on the original brand's approval.

Example

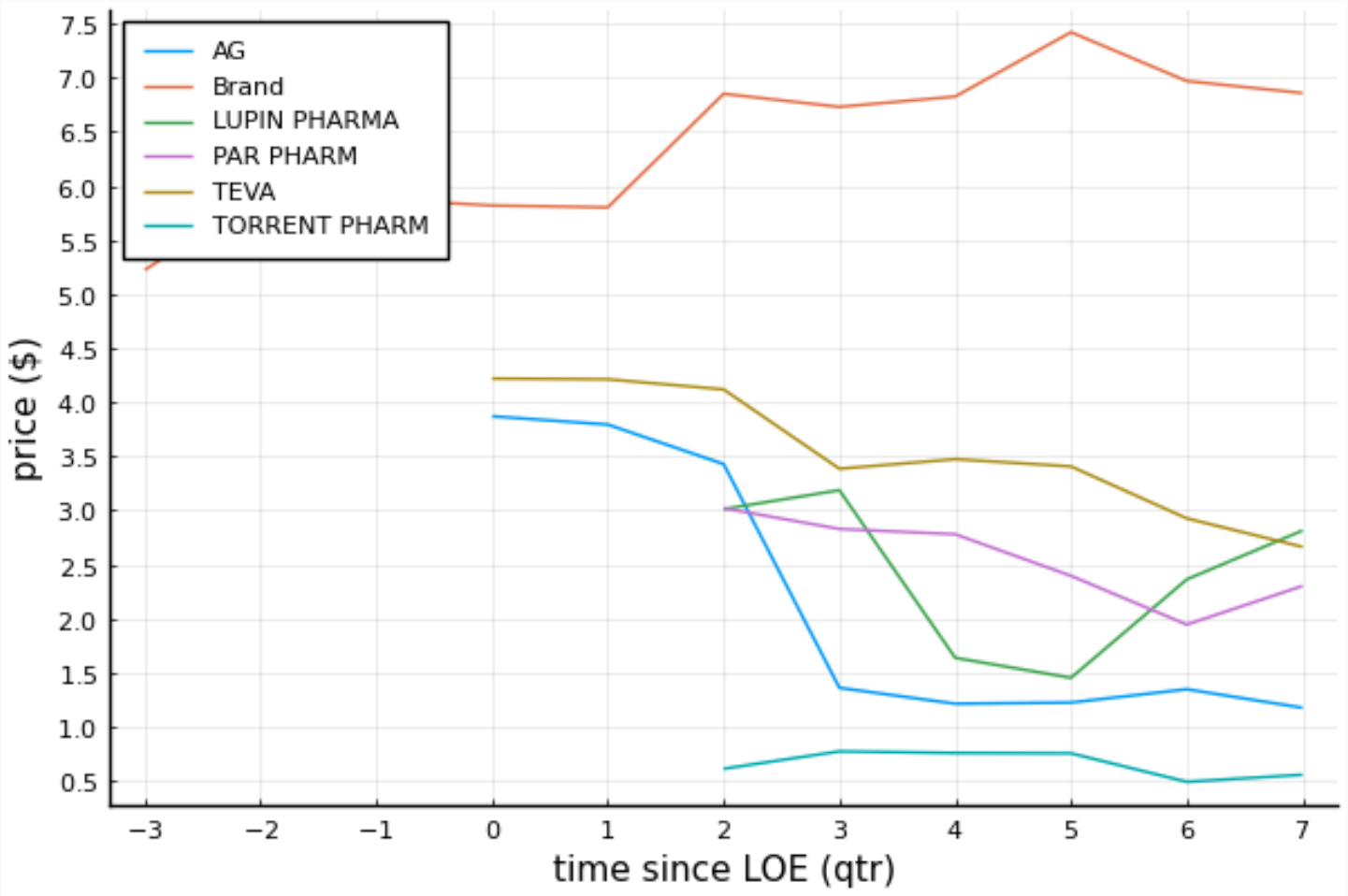

Figure 1: US-average prices for amlodipine-hydrochlorothiazide-valsartan (oral)

Example

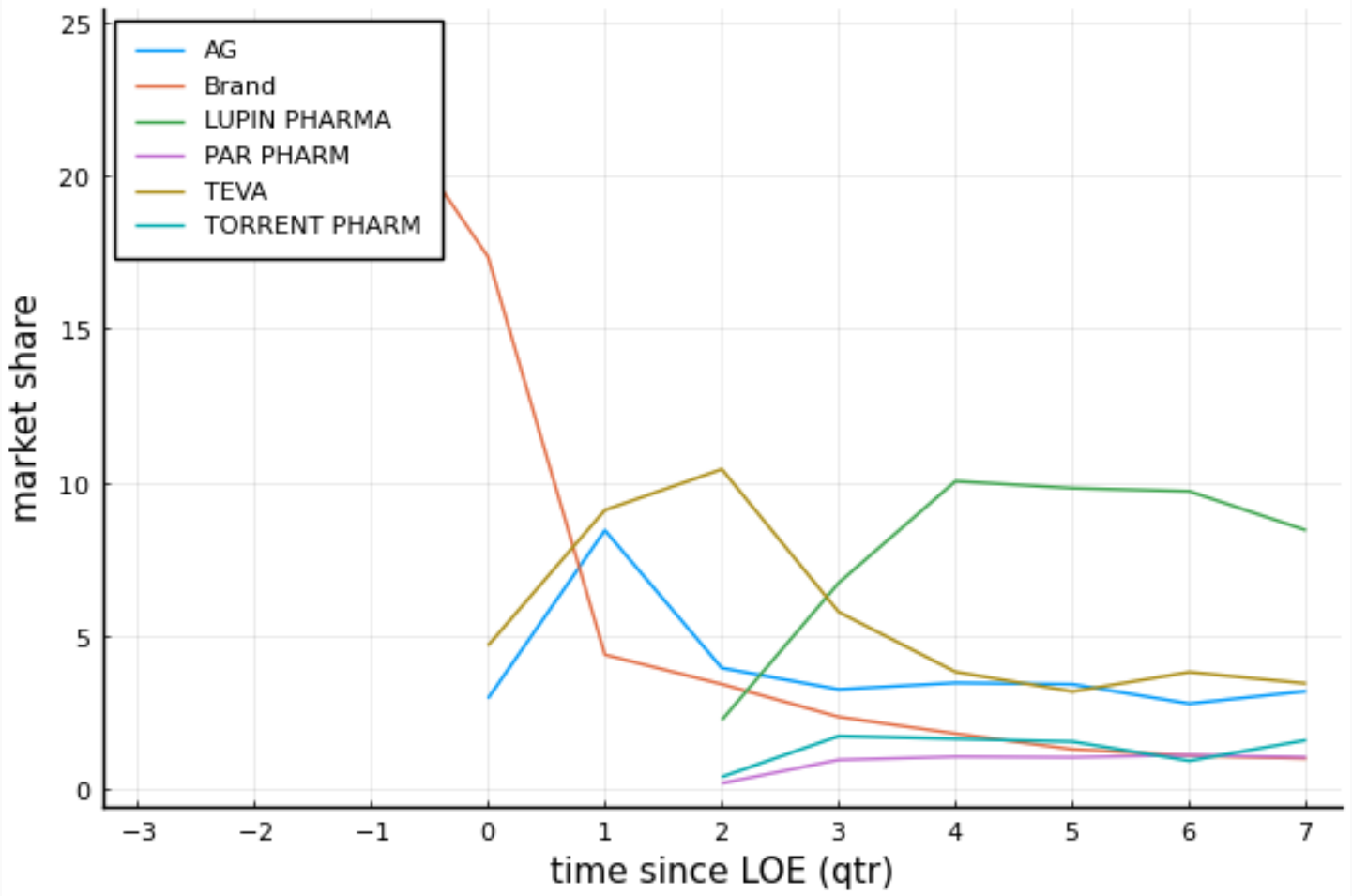

Figure 2: Market shares for amlodipine-hydrochlorothiazide-valsartan (oral)

Entry and pricing with AG

What rationalizes this pricing and product line response by the incumbent?

- Heterogeneity in brand-valuation and price-sensitivity among consumers.
- Only consumers with high brand-valuation and low price-sensitivity buy the brand, and so brand can charge them high prices without losing them.
- Consumers with low brand-valuation and high price-sensitivity buy generics, so releasing fighting brands allows the incumbent to capture some of the profit from this segment of the market too.

Research question

Build a structural model of demand, pricing and entry of pharmaceuticals after loss of patent protection.

Questions to answer:

- Quantifying level of heterogeneity in brand valuation and price sensitivity in demand for pharmaceuticals.
- Do AGs get a "quality" premium in the demand function?
- How pricing and entry decisions by incumbent and generics depend on demand primitives.
- Effect of AG on generic entry and pricing decisions (e.g. "chilling effect").
- Effect of speeding up generic approval rate.

Motivation

Why is this useful?

- Policy discussion regarding high drug prices.
  - Major price declines happen after generic entry.
  - Studying this can help us understand market dynamics and craft better policy.
- Contribute to nascent empirical IO literature on **fighting brands**.
  - Widely observed in various industries.
- Policy discussion surrounding banning Authorized Generics.
  - First to build a rational expectations framework that embeds generics and AG predicting each others' choices when making decision.

Data

Data from IQVIA for 2004-2016 on USA. Sales are aggregated to US, e.g. how many units of Lipitor tablet was sold in US in 2009Q1.

- Quarterly sales of each drug in US
- Revenue of each drug (gives me price)
- Formulation of product (oral, injectable, etc.)
- Therapeutic class
- Active ingredients

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

Data

To set expectations for the rest of the seminar:

- We only have sales data at US-quarter level.
- We use this to study *aggregate* industry dynamics like average price in US, entry decision, etc.
- We cannot look at finer variation like pricing and inclusion across insurance plans.
- The demand side of the paper is thus a mix of pharmaceutical intermediaries and consumers jointly making a purchase decision. We do not try to distinguish them or their individual payoffs; only their joint demand is modeled.

Market definition

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

After data-cleaning,

- 246 molforms, each followed for many quarters before and after LOE.
- 110 molforms see AG released.

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

Structural model: Demand

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

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

We estimate this using the method of Berry-Levinsohn-Pakes (1995):

- Gandhi-Houde IVs
- 2-step GMM

Structural model: Supply

A model with two stages:

1. First stage: From a pool of potential entrants, generic firms decide whether to enter a market or not.
    - Static entry game.
    - Entry decision is implemented randomly with median time of 40 months.
2. Second stage: Loss-of-exclusivity happens and dynamic game begins. Every period,
    - A random number of the generic firms which chose to enter are introduced into the market.
    - Brand manufacturer chooses price of its branded product (static effect) and decides whether to release AG or not (dynamic, irreversible).
    - Price competition between brand, generic and AG.

Structural model: Supply

The branded drug manufacturer's per-period payoff is:

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

The generic firm l's per-period payoff is:

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

Nash-Bertrand pricing between generics and AGs.

Price fixed at observed level for brand.

Structural model: Supply

Let n_e^* be the number of generic firms that have applied for an ANDA (which is determined in the first stage).

In period $t = 0$ the branded drug's patent expires, and every period a random number of generic firms gain FDA approval and enter the market.

A discrete game begins from $t = 0$ and lasts T periods, where every period is a quarter.

Structural model: Supply

The value function for a branded drug manufacturer every period is given by:

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

Similarly, the value function for generic l is given by:

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

where $s_{l,t}$ includes whether generic l has been approved for production by the FDA.

Structural model: Supply

After period T, the industry state is set at s_T, and 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:

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

Structural model: Supply

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

Note that we assume the equilibrium number of generics that applied for ANDA n_e^* is known to the branded drug manufacturer from $t = 0$.

Structural model: Supply

In the first stage, an infinite number of generics decide if they want to enter.

We assume all generic firms are ex-ante identical, do not receive private error draws for entering and staying out, and do not know their draws of ξ_{jt} conditional on entry.

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

Results from demand estimation

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

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

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

Counterfactuals

Nonbrand coef	Total generics	AG release fraction	AG price	Generic price	Per-Generic share	Brand share	AG share
-2.4	13.0	1.0	2.74	2.69	6.92	0.72	9.37
-2.88	11.0	1.0	2.76	2.71	8.02	0.95	10.83
-3.37	9.0	1.0	2.78	2.72	9.54	1.28	12.84
-3.85	7.0	1.0	2.82	2.75	11.79	1.79	15.71

Table 2: Market outcomes with changing non-brand coefficient.

Counterfactuals

Nonbrand variance	Total generics	AG release fraction	AG price	Generic price	Per-Generic share	Brand share	AG share
2.37	6.0	0.0	0.0	2.73	15.77	5.41	0.0
2.7	8.0	0.05	2.73	2.74	10.48	3.16	13.0
3.04	9.0	1.0	2.74	2.69	9.39	2.72	12.8
3.38	10.0	1.0	2.75	2.69	8.6	2.29	11.71
3.72	12.0	1.0	2.73	2.69	7.34	1.9	10.01

Table 3: Market outcomes with changing variance on non-brand's random coefficient.

Counterfactuals

Price coef	Total generics	AG release fraction	AG price	Generic price	Per-Generic share	Brand share	AG share
-2.41	9.0	1.0	3.29	3.17	8.87	8.41	11.75
-2.72	6.0	1.0	3.04	2.94	12.88	5.62	17.11
-3.02	4.0	1.0	2.88	2.79	18.13	3.67	23.82

Table 4: Market outcomes with changing price coefficient.

Counterfactuals

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 5: Market outcomes with changing operating cost of AG.

Counterfactuals

MC of AG (normd)	Total generics	AG release fraction	AG price	Generic price
1	4.0	1.0	2.88	2.79
2	5.0	1.0	5.3	2.85
3	5.0	1.0	7.95	2.88

Per-Generic share	Brand share	AG share
18.13	3.67	23.82
18.42	3.6	4.3
18.98	3.69	1.41

Table 6: Market outcomes with marginal cost of AG.

Counterfactuals

Generic entry 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 7: Market outcomes with changing FDA approval rates.

Counterfactuals

Cases	Total generics	AG release fraction	AG price	Generic price	Per-Generic share	Brand share	AG share
Baseline	4	1.0	2.88	2.79	18.13	3.67	23.82
AG ban	5	0.0	0.0	2.91	19.25	3.75	0.0

Table 8: Market outcomes with and without AG ban.

Conclusion

We analyze pricing and product line response by brand incumbents in pharmaceuticals facing entry by competitively-priced generics.