R&D PRODUCTIVITY, SPILLOVERS AND EFFECTIVE PATENT LIFE

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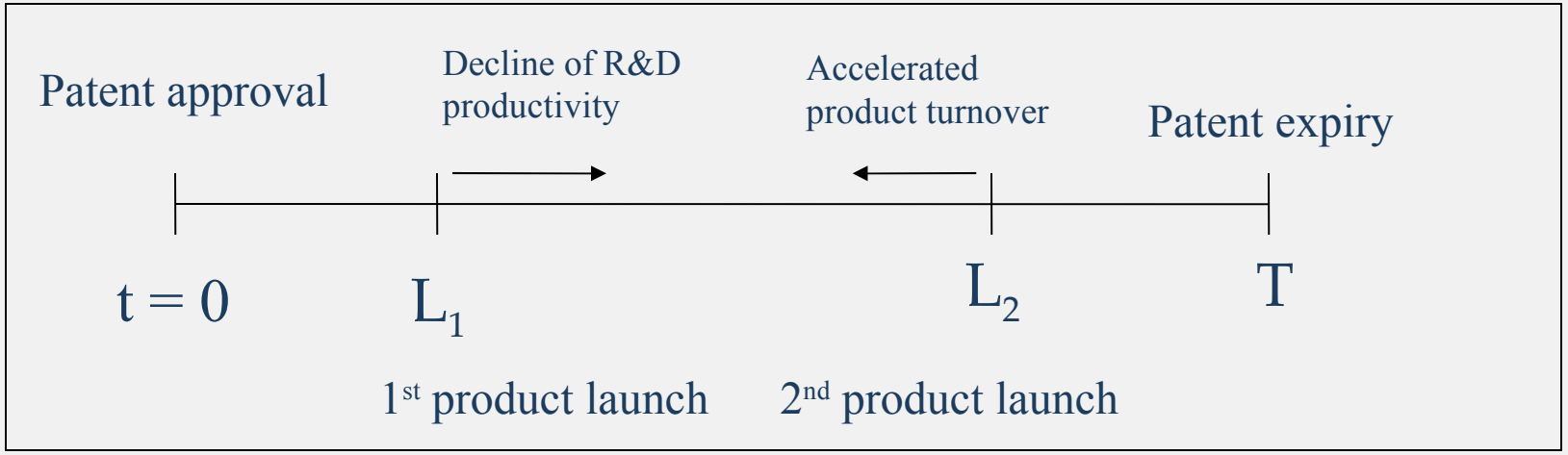
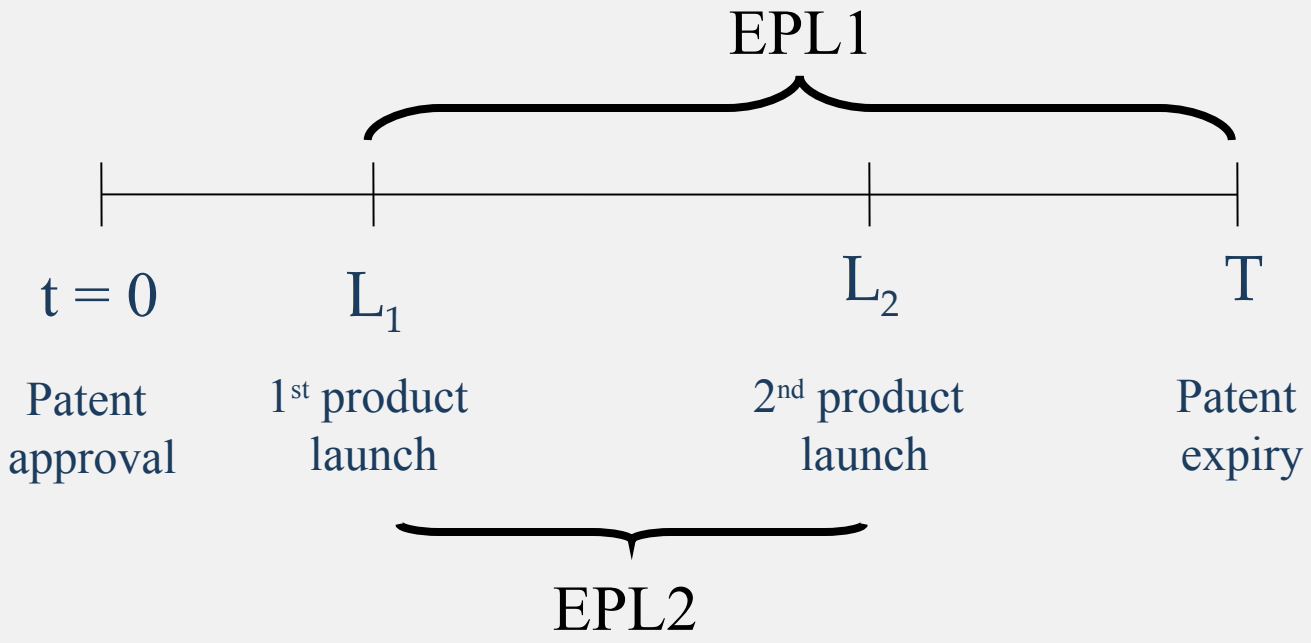
Aim of the paper

- Pharmaceutical R&D
  - Slowdown in productivity
  - Increasing complexity
  - Increased market turnover
- What effect on the market value of patents and incentives to innovate?
  - Effective patent life
  - Sales turnover and follow-on competition



How to measure Effective Patent Life?

- EPL1: from product launch to patent expiry
- EPL2: from product launch to the next in-patent competitor
- EPL3: jointly consider EPL1 and EPL2 taking into account sales erosion due to follower entry (between patent competition)



A simple two-stage game

1. R&D race to discover and patent a new product candidate
   - » Firms choose among k(t) research trajectories, thus defining the features of the candidate product
   - » Degree of correlation among success probabilities
1. Testing phase and approval for marketing
   - » Duration is purely stochastic with instantaneous probability of success λ along each trajectory
   - » A patent is issued at the beginning of the phase and lasts T periods
   - » Within this framework, label $(1 - \beta)$ as the patent breadth, i.e. β represents the level of dissemination of knowledge allowed by the patent (knowledge spillovers -- Denicolo, 1996)

» We will consider 3 different cases characterized by different level of competition and spillovers

CASE I. Patent exclusivity & no spillovers (1)

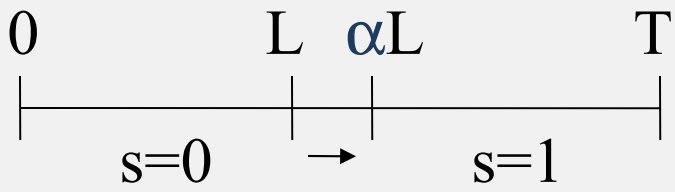
- Only one patent at a time, "winners take all" hypothesis, or $L<T\leq 2L$ (no overlapping patent terms), no spillovers $\beta=0$, no between patent competition. Let's take $c=r=0$.
- $s=0$ before product arrival (R&D phase) while $s=1$ after product launch (market exclusivity regime) until T.
- We suppose that the expected social value of undertaking R&D is positive:

$$v(T-L)-C > 0 \text{ or } v/C > 1/(T- L) \qquad (1)$$

- BUT $sv(T-L)-C < 0$ with $s = 1/n$ in case of n coexisting patents (each take the same share of total value v or have the same probability to get the patent).
- Classic incentive failure the patent system is meant to address

CASE I. Patent exclusivity & no spillovers (2)

» Let's assume that the R&D productivity decreases so that the expected arrival time is now αL ($\alpha>1$) and $\alpha L<T\leq 2\alpha L$, otherwise the condition (1) will not hold.



$V=(T-\alpha L)v$

$\Delta V= -(\alpha-1)Lv= (1-\alpha)v/\lambda$ negative effect (patent erosion)

PROPOSITION 1:
An increase in R&D complexity decreases EPL1

CASE II. between patent competition & no spillover

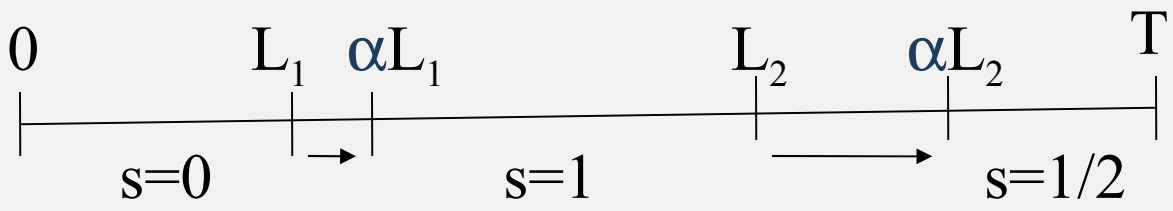
» Now we allow between patent competition ($T > nL$), still with perfect patent protection ($\beta=0$).

» Let L_i be the arrival time of the *i*-th patented product into the market

» Assuming Poisson process with instantaneous probability λ:

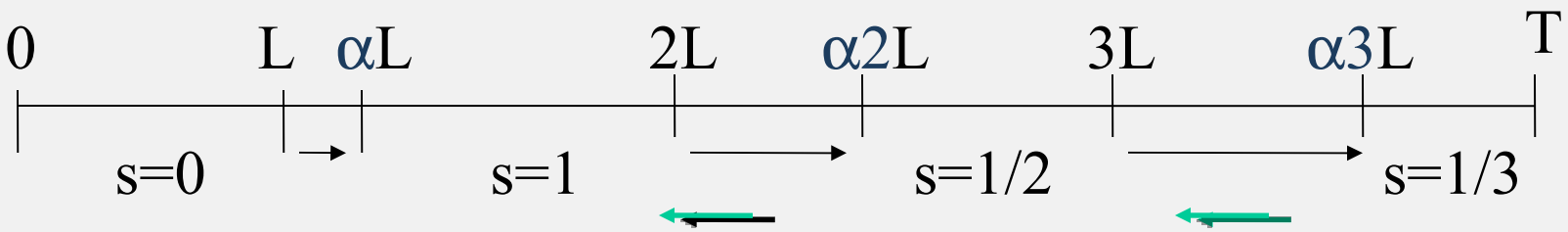
$$\Pr(L_2 > L_1 + t \mid L_1 = 0) = \exp(-\lambda t)$$

» Consider a decline in R&D productivity α ($\alpha > 1$), assuming $\alpha L_2 < T$.



PROPOSITION 2: In a high λ regime, an increase in R&D complexity implies an increase of EPL2 (conditioned upon product launch)

CASE III. between patent competition & spillovers



» Patent breadth is $0 \leq 1-\beta < 1$: parallel R&D projects can be correlated

» Increasing level of β can counterbalance the increase in complexity (conditioned upon first arrival)

PROPOSITION 3: In a high λ regime with $\beta > 0$, growing R&D complexity and between patent competition, firms will select too correlated R&D projects and EPL2 will decrease

Empirical Analysis

- Source of the data: CERM database on the activities within the pharmaceutical industry
  - a) R&D: patents and drug development projects; publications
  - b) Market: product sales in major markets (EU-15 & US)
    - Linked to FDA information on priority/standard review
    - Linked to disease classification: severity, diffusion, difficulty of related research
- Method: duration and regression analysis
  - Time from patent filing to market launch (EPL1)
  - Time from market launch to follower entry (EPL2)
  - Sales erosion due to follow-on entry (EPL3)

Measuring complexity and spillovers

- Complexity
  - R&D Trajectories
  - Organizational complexity
  - Regulatory complexity
- Spillovers
  - Patent citations
  - Co-authored publications
  - Order of entry into the market

Empirical analysis: Main results

- The R&D productivity slowdown (organizational and regulatory complexity, increased number of available trajectories) is driving up EPL1
- EPL2 is positively affected by increased complexity, whereas knowledge spillovers exert a negative effect
- Sales erosion
  - First mover advantage
  - Increased price competition in latest years

Patent Erosion (Δ Months) in selected countries, 1993-2007

Country		EPL_1	EPL_2	EPL_3
EU-15	Launched in 1993	105.9	46.9	93.8
	Launched in 2007	80.5	48.2	73.7
	$\Delta_{(EPL_{07}-EPL_{93})}$	-25.3	+1.2	-20.1
	Avg. Δ	-1.7	+0.1	-1.3
USA	Launched in 1993	95.7	47.7	85.5
	Launched in 2007	70.6	44.1	64.9
	$\Delta_{(EPL_{07}-EPL_{93})}$	-25.1	-3.6	-20.6
	Avg. Δ	-1.7	-0.2	-1.4
Total	Launched in 1993	105.2	47.0	93.2
	Launched in 2007	79.9	48.1	73.1
	$\Delta_{(EPL_{07}-EPL_{93})}$	-25.3	+1.1	-20.1
	Avg. Δ	-1.7	+0.1	-1.3

Summary and conclusions

- We have developed a model of patent term erosion in the context of decreasing R&D productivity and spillovers
- In the context of the pharmaceutical industry:
  - Evidence of significant spillover
  - Patent term erosion over time
  - Dynamics in between-patent competition
- Implications for patent term restoration

Thank You

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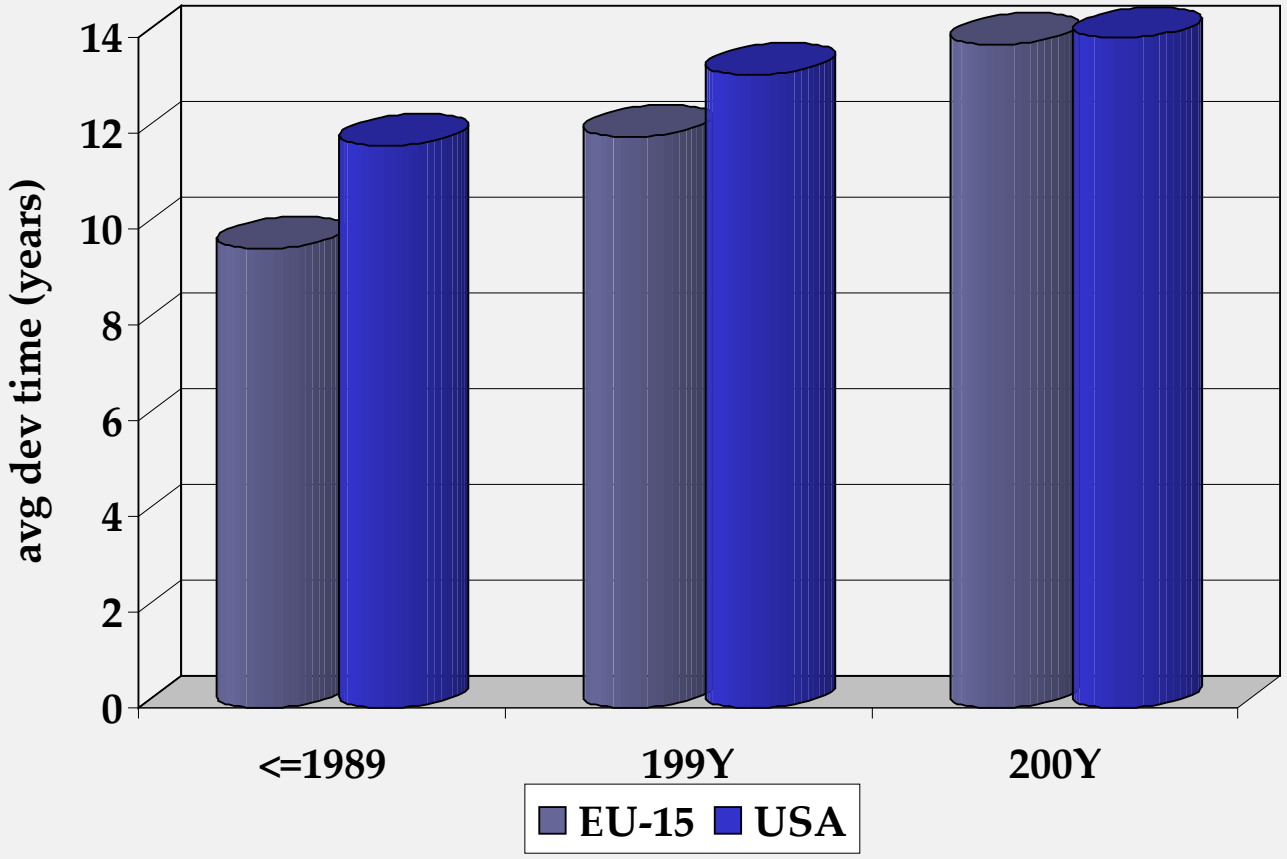
EPL1: increasing time to marketing approval
Descriptives



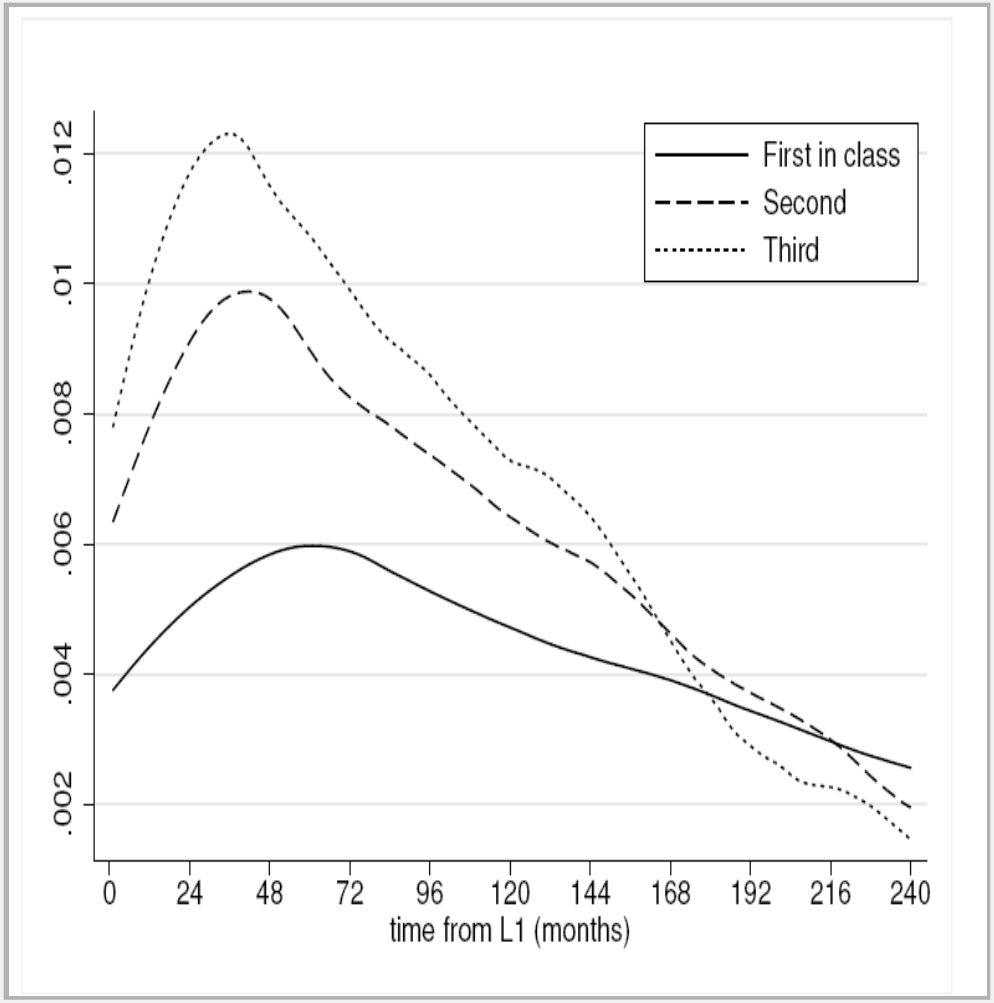
EPL1: increasing time to marketing approval -- *Duration analysis*

Variable	Model 1	Model 2	Model 3	Model 4	Model 5[(a)]
Trend	0.0141***	0.0132***	0.0128***	0.0141***	0.0147***
	(0.0013)	*(0.0013)*	*(0.0013)*	*(0.0013)*	*(0.0025)*
R&D Trajectories		0.0334***	0.0297***	0.0700***	0.0871***
		(0.0071)	*(0.0071)*	*(0.0083)*	*(0.0183)*
License			0.1549***	0.1551***	0.2341***
			(0.0106)	*(0.0105)*	*(0.0211)*
Outcome				-0.1224***	-0.4011*
				(0.0314)	*(0.2052)*
Organ damage				-0.0275	-0.2940
				(0.0299)	*(0.2045)*
Complications				0.0659**	-0.2066
				(0.0326)	*(0.2035)*
Chronic				-0.1144***	-0.0532
				(0.0330)	*(0.1237)*
Constant	5.028***	4.891***	4.833***	4.809***	4.368***
	(0.0218)	*(0.0389)*	*(0.0388)*	*(0.0091)*	*(0.2874)*
Country FE	yes***	yes***	yes***	yes***	yes***
$\ln(\sigma)$	-0.7787***	-0.7841***	-0.8002***	-0.8124***	-0.6979***
	(0.0088)	*(0.0090)*	*(0.0090)*	*(0.0091)*	*(0.0154)*
κ	0.6238***	0.6258***	0.6343***	0.6568***	0.5548***
	(0.0222)	*(0.0226)*	*(0.0226)*	*(0.0232)*	*(0.0402)*
Log lik	-5396.00	-5137.87	-5032.18	-4976.74	-1873.61
N	7,660	7,345	7,345	7,345	2,427

EPL2: Market exclusivity & spillovers

Descriptive analysis

Time span	% still under market exclusivity (whole sample)
1 year	77.75
4 years	47.27
8 years	32.91
10 year	28.81



EPL2: Market exclusivity & spillovers

Regression results

- EPL2 is a decreasing function of spillover
  - Negative effect of SP(patent)
  - Negative effect of SP(publications)
  - Negative effect of order of entry
- EPL2 is an increasing function of R&D complexity
  - Positive effect of the number of R&D trajectories
  - License dummy is positive and significant
  - Upward trend
- Limited evidence about the effect of market characteristics

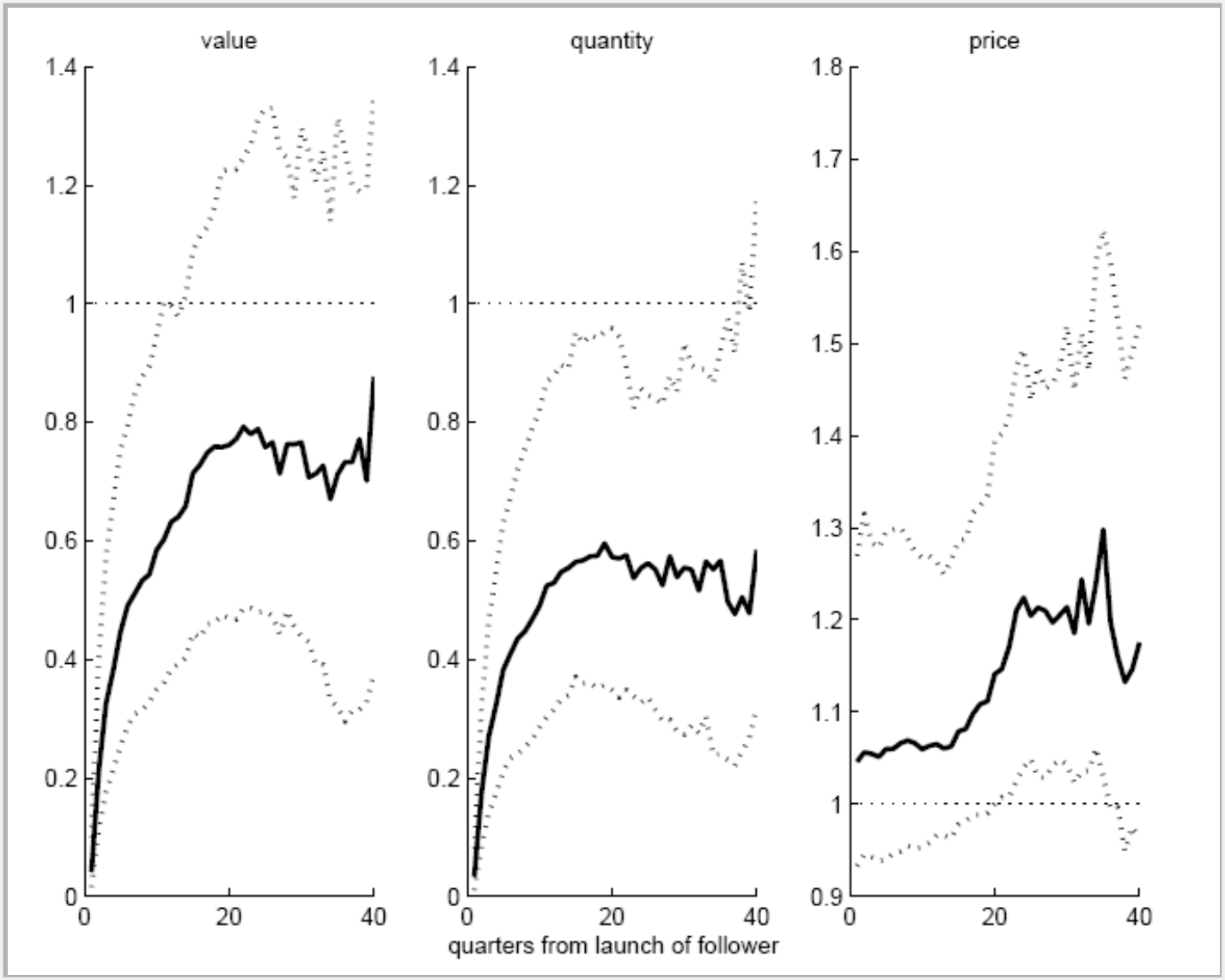
Intensity of between-patent competition (1)

- Model of technology diffusion (Fisher, Pry, 1971; Peterka, 1977)
- Let f_{1t} be the market share of innovator at time t and f_{2t} be the market share of competing (younger) technology
- $t = 0$ is the time when the period of market exclusivity of compound 1 ends with the entry of compound 2
- Penetration of the new technology is measure as a function of the ratio f_{2t}/f_{1t}
- Simple modeling: for each product i we consider

$$\ln [f_{2t}/f_{1t}] = a_i + b_i\, t + u$$

- The larger b_i, the faster competitor diffusion and innovator sales erosion
- The model is also applied to price ratios

Intensity of between-patent competition (2)



Between-patent competition (3)

Launch year of innovator	Average Estimated b_i	Median Estimated b_i
Sales Value		
1993-1997	0.0584	0.0565
1998-2002	0.0698	0.0609
2003+	0.0892	0.0510
Quantity		
1993-1997	0.0590	0.0553
1998-2002	0.0694	0.0611
2003+	0.0905	0.0551
Median Price Ratio (1st year)		
1993-1997	1.0469	
1998-2002	1.0402	
2003+	0.9952	