Economic Developments in the Analysis of Pharmaceuticals Mergers

A European Perspective

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Where is the analysis going in Europe?

Traditional analysis: "pipeline competition" - do parties have "concrete" plans to develop molecules serving a similar purpose?

Mostly "rule of thumb" divestment of overlaps. In *a few* cases economic analysis to quantify

- Incentives to withdraw the weaker product and identify factors pushing in the other direction (e.g. by conducting financial modelling of the pay-off from delayed entry)
- …and quantify potential ex-post price effects (e.g. by modelling future horizontal competition and potential offsetting complementarities)

NEW WORLD: focus on "innovation competition" ("R" in R&D")

- **"Upstream" competition in innovation.** Framework of *Dow/Dupont*
  - Evolution of "innovation markets": concern not about specific future product overlaps, rather general **incentive to innovate**
  - **Internal documents key**, but **economic analysis can assist with this exercise**
  - Can **identify market features that counteract innovation effects and conduct patent/ citation analyses to identify competitive constraints in this space and areas of concern**
- **"Killer acquisitions".** Not yet come up BUT ***established policy concern following seminal paper.***
  - **Clear evidence <u>this happens.</u>** Again internal documents and patent analyses will be key.

Typical analysis of pipeline issues (e.g. J&J/Actelion, Novartis/GSK…)

Standard theories of harm: **cancellation/delay of the "weaker" product** (=> higher prices and reduced choice) and **reduced future price competition** (=> higher prices)

Issues to be explored	Argument	Analysis/Comments
Other existing and potential competitors?	If estimated potential profit diversion is small,, incentive to cancel a project more limited	Can use patent data to identify potential entrants and adapt price-based unilateral effects analysis to assess these incentives
Complementarity?	Offsetting effects if drugs could be used in combination in certain use cases	Fact specific, but arguments got traction for current overlaps in GSK/Novartis
Low success chances for weaker product?	If one drug is "far up" the pipeline then probability of getting to market (and hence any effects from cancelation) will be small	Model effects using data on approval rates/timing at each development stage
Low joint chances of success?	If both parties' products far up the pipeline chances of there ever being head-to-head competition is likely to be negligible	Same modelling effect as above, but "failure" rate at each stage is "compounded"
Limited patent- phase competition?	Depending on regulatory system, price constraint from similar, patented drugs may be small	Can confirm using econometric analysis (price-concentration, entry exit)

A new “innovation” focus

Innovation as main focus – valued in policy terms as “engine” for economic growth

Legitimate to evaluate effects of mergers on innovation incentives and outcomes - why only worry about ACTUAL overlaps and price effects? What if the biggest welfare effects arise from **slowing the target’s innovation effort, or killing it altogether?**

Two key developments:

1. **“Innovation theories of harm”** in agro-chemicals (“unilateral effects in innovation”: internalising competition in innovation, like in price)
2. **“Killer acquisitions”** paper (suppression of future potential entrant/threat altogether) – presents clear alternative to standard benign view that acquisitions of small innovators *enables* them to flourish (better execution capabilities, scale, synergies increasing overall welfare)

Innovation theories of harm (ex Dow/Dupont)

In industries where: i) focus is on product innovation; and ii) there is effective IP protection, mergers in concentrated markets can be expected to reduce innovation unless they generate offsetting synergies.
Is this a presumption? NO. EC recognised one is trading off three effects:

Innovation competition effect	Product market effect	Appropriability effect
• Innovation partly motivated by winning sales from rivals • Merger "internalises" this to extent sales would be won by the merging party • Concern about "cannibalisation" reduces incentive to innovate • *This is just like a traditional price effect and acts to reduce innovation*	• What if the merger increases market power in the product market? • Acts to raise profits both with and without innovation • So effect on innovation incentive ambiguous • *EC argues this effect should be small if product market remedies effective.* • ***And not a particularly attractive argument!***	• Innovators need to be able to "appropriate" innovations via higher future profits • A merger could promote innovation by removing a "copycat" and increasing the scale over which benefits can be realised • *EC argues this effect irrelevant when IP rights strong and if focus is on product, rather than process, innovation*

How to think about this?

Huge resistance from the bar and “some” economists: from “picking winners”, “gazing into the crystal ball”, to “the CET model is not robust if I change XYZ assumption”.

It is not a presumption, but to say that theory is completely agnostic, cannot “sign” anything and “everything goes” is disingenuous. Disingenuous to say that because there is uncertainty on research outcomes we cannot intervene.

Think of it this way: **innovation can be harmed when research is a “race” and the parties that are neck-to-neck in the race merge.**

Robust economic insight is that **firms RACE against each other to ESCAPE COMPETITION**. When competition is head-to-head there’s a big incentive to innovate to pull away. Competition is good for innovation bcs we want to escape it

All you need to know from theory.

The real issue is not theory, but *standard of proof*

Evidence?

- Are parties closely competing in same race?

- In Dow/DuPont, analysis of **patent citation counts:** Identify which patents should be considered in the same use group, then calculate increment in share of patenting activity. **Do parties cite each other disproportionately? Are they genuinely competing in a race or is one party a follower? Are the parties patterns of citation particularly similar to each other**?

Returns to winning? The higher they are prospectively, the more likely the merger will stop the race.

- Returns to winning are *lower* if multiple molecules could treat the same condition, and *higher* when process patents are stronger, when there is inertia in prescription practices…

Internal documents key

This said, HARD: efficiencies very hard to prove in this space (more so than costs) – so we do not want to lower the standard of proof for R&D theories relative to price effects, while keeping the same hard standard for showing efficiencies…..

"Killer acquisitions"

Seminal paper 2018 (Cunningham (LBS), Ederer & Ma (Yale)) – inspired by Questcor/Mallinkrodt, highly regarded as the best policy paper of last couple of years.

Intuition: innovative small companies are targeted for acquisition to discontinue the development of projects that may turn into serious threats and preempt future competition "cannibalizing" existing products and profits. "Buy, and then kill".

Study: Tracked detailed project-level development for >35,000 pharmaceutical drug projects by 6,700 companies over 25 years. Followed project pre and post acquisition

Key findings:

1. **acquired drug projects are less likely to be developed when acquired project overlaps with the acquirer's portfolio of products and projects (development rate decreases by 40%)**
2. **pattern more pronounced when the acquirer has strong incentives to protect its market power i.e. existing competition is weak.**

Alternative interpretations? ***Tested for: "optimal project selection", "delayed development", "human capital and technology redeployment"-*** **but these do not explain away results.**

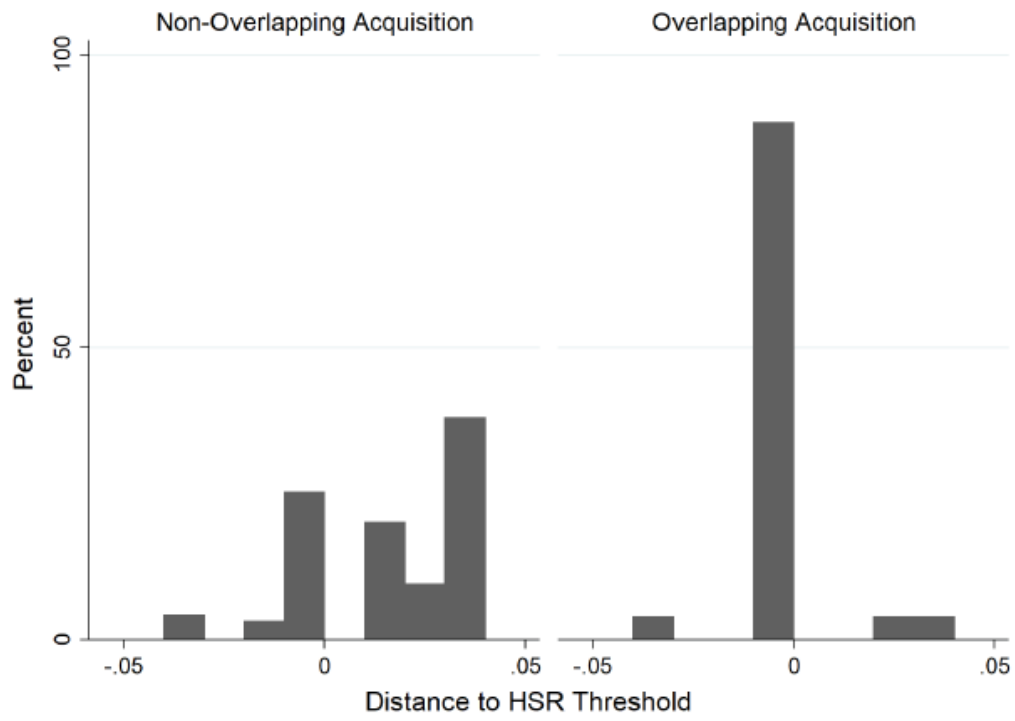
Conclusions: about 6% of acquisitions in the sample were real "killer acquisitions"

Key finding: most deals below antitrust review threshold

"Our analysis reveals that acquirers conducting killer acquisitions are much more likely to undertake deals that do not trigger FTC notification requirements for pre-merger review and thereby avoid antitrust scrutiny".

"Acquisitions of overlapping targets bunch just below the FTC acquisition transaction value threshold, while there is no such pattern for non-overlapping acquisitions. In addition, these below-threshold deals exhibit much higher termination rates and much lower launch rates".

- Evaluating acquisitions near the HSR reporting threshold:



- Drug launch rate 10% below vs above threshold: 1.79% vs 9.09%

Why do we care so much? Policy implications

Seen as validation of "innovation theories of harm": confirms that **protecting existing profits provides an incentive not only to slow own replacement innovation but also to suppress others' innovation**

This is **most true in situations where there is already low competition – more concentrated markets**

Incumbents are careful to fly below the radar

But key is the finding that **eliminating the adverse effect on drug project development from killer acquisitions would raise the pharmaceutical industry's aggregate drug project development rate by nearly 5%.**

Conclusions

Focus MUCH more on "upstream" activity ("the "R" in "R&D"") because of recognition that what matters is innovation effort for future growth and welfare.

European bar up in arms "the Commission is gazing into the crystal ball", "picking winners", etc.

WHEN IN FACT these are the same voices that criticise the Commission for being "myopic" and only considering price effects in mergers that are "tranforrmative".

WHEN IN FACT the mechanisms are at least conceptually very clear and legitimate.

Mistake (and intellectually dishonest) was to argue these effects should not be considered EVEN IN PRINCIPLE because "it's all very uncertain and you cannot tell".

ISSUE is only standard of proof, not whether these effects can exist.