EU Merger Control in the Pharmaceutical Industry

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September 23, 2014

Competition over the life cycle

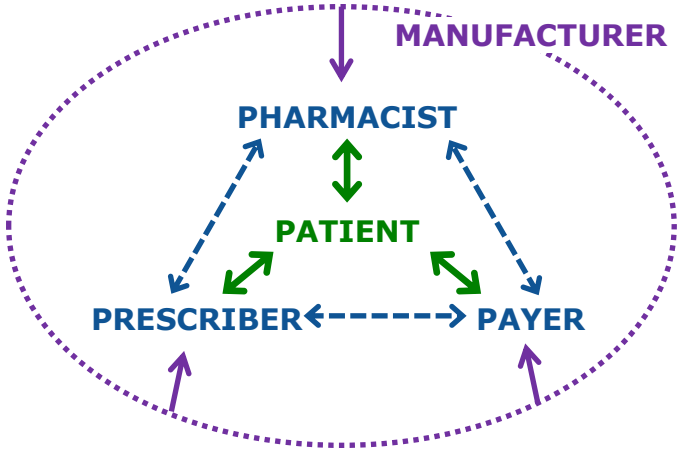
- Three stages in the life cycle of a pharmaceutical product:

- Mergers, JVs and competition between…
  - Originators: likely to involve products at every stage in life cycle
  - Originators and small research firms: mainly pipeline products
  - Originator and generic: products mainly close to off-patent and already off-patent
  - Generics: off-patent products

Firms compete in a number of ways

- Through innovation:
  - To develop new or better products, first-mover advantage
- Product differentiation (other than through innovation):
  - Through clinical trial evidence, i.e. efficacy, safety profile
  - Positioning in therapeutic pathways, i.e. clinical guidelines, clinical practice
  - Advertising, detailing
- Price & Reimbursement conditions:
  - Relative prices relevant for prescription guidelines
  - Cost-effectiveness assessment, e.g. UK's NICE
- Generic competition:
  - Mainly price competition (homogeneous products)
  - Second generation products, ever-greening, patent settlements – antitrust

Identifying significant competitive constraints



- Challenge: identifying which products compete – demand-side substitution
- The demand for drugs is complex:
  - Multiple decision makers
  - Manufacturers influence decision makers (within regulated limits)
- Substitution patterns are an empirical question
  - Functionality as a starting point – mode of action, indications, therapeutic guidelines, line of treatment
  - But actual substitution patterns only imperfectly characterized by functionality – product market may be broader or narrower than ATC3
  - How does the demand respond to changes in relative prices, quality, advertisement effort? – observe market outcomes
- In mergers, current competitive constraints as starting point – unlike antitrust

Competitive constraints evolve over the life cycle

Let's look at it backwards…

- Upon generic entry (close to and after loss of exclusivity on compound):
  - Typically observe significant price reductions and shift of demand away from originator – generics constrain originator through price competition
  - No advertising – little effort to differentiate originator from generic, homogeneous products
- During market exclusivity:
  - Prices typically stable (often regulated), well above marginal cost
  - Intense advertising to differentiate from other originators' products – non-price competition between differentiated products
- Before market launch:
  - Market outcomes not yet observed – Functionality and players' expectations are the main evidence available
  - Potential future competitors – innovation competition

Effects on actual, potential and innovation competition

- Actual competition:
  - Based on observed overlaps in the market
- Potential and innovation competition from products in the pipeline:
  - Products in the pipeline are likely future competitors
  - Finite number of pipeline products with potential to compete in the future
  - Mergers can modify incentives to continue developing certain products – concern if a line of research may be abandoned after merging
  - Not only competition between marketed and pipeline products, also between pipeline products
- Potential competition from generics:
  - Typically more than one potential generic entry
  - However, not all generics are equally close potential competitors for the originator, i.e. generic firms asymmetric in their capabilities
  - Concern if the merger eliminates the generic most likely to enter early

What's different for OTC?

- Different role of decision makers
  - Higher patient autonomy in product choice
  - Direct-to-consumer advertising – interaction patient-manufacturer
  - Lesser role for the prescriber and the payer, stronger pharmacist influence
- Greater patient autonomy results in greater importance of brands
  - More brand recognition by the patient
  - Customization of products to patient preferences – greater importance of non-clinical aspects
  - Importance of brand differentiation beyond loss of exclusivity, more limited impact of generic competition
- Wider range of distribution channels in some countries – non-pharmacy stores
- Same approach to identify competitive constraints – market evidence to characterize substitution patterns

In fact, no size fits all…

- Biosimilars
  - Not automatically substitutable – unlike generics, biosimilars are differentiated products
  - Impact of biosimilar entry likely to vary across products
- Vaccines
  - No generics for vaccines
  - But ability to differentiate may be limited – tendering, public procurement
- The approach to identifying competitive constraints consistent across types of products, but taking into account the specifics of each case – different results for different situations

Aspects of EC assessment in previous pharma M&A

- On market definition:
  - Therapeutic categories taken into account as starting point, but also single indications, type of patient – not a mechanical ATC3 approach
  - Segmentation case by case, e.g. oncology field
  - Market data used to identify substitution patterns, e.g. GSK/Stiefel (2009)
- Potential competition from pipeline products taken into account, e.g. Merck/Schering-Plough (2009)
  - Including areas where both parties had only pipeline products
- On generic competition, asymmetries between generic companies taken into account when assessing closeness of competition, e.g. Sanofi-Aventis/Zentiva (2009) and Teva/Cephalon (2011)

The current wave of pharma M&A

- A number of notifications expected in a variety of areas:
  - Prescription drugs (on- and off-patent)
  - OTC drugs
  - Vaccines
  - Animal health products
- Assessing competitive constraints in pharma not fundamentally different from other industries
  - It is about identifying products that compete or may compete in the future – an empirical question
  - Specificities to be taken into account: complexity of demand, price regulation, market access, exclusivity rights
- As in any innovative industry, a dynamic perspective is needed: market outcomes today and expected market outcomes tomorrow