EU Merger Control in the Pharmaceutical Industry

Paul Csiszár
Director, DG Competition, European Commission

Global Antitrust Institute, George Mason University School of Law
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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