Innovation and EU merger control - a new approach?

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The European Commission is increasingly taking action on the grounds of an adverse impact on innovation in merger situations. The Commission's approach to innovation as a stand-alone theory of harm is increasingly rigorous. This change in approach has been shown in a number of recent cases. As a result, in some merger situations, businesses are pre-emptively divesting research and development (R&D) streams in order to avoid regulatory scrutiny.

The Commission has started to look beyond parties’ existing pipeline products (ie those products that have already reached the test phase of the development process) and focusing on products that could potentially be developed in the future. This is of relevance to any company with high levels of R&D (for example, in the TMT and pharmaceutical sectors) that may want to merge with a firm that could potentially produce similar products.

Tommaso Valletti, who was appointed in 2016 as the European Commission’s chief economist, recently co-authored a research paper that concluded that mergers between innovators may lead to a reduction in innovation across an entire market and not only in relation to products of the merged entity.

The Commission and practitioners largely agree that the analysis of a merger of a company with a pipeline product (for which practically all of the innovation work has been completed) and another company with an existing product, is essentially no different to the analysis of a merger of two companies with existing products.

However, recent cases have shown that the Commission has started looking further into the development stages of a company’s pipeline products in order to assess whether there will be an adverse impact as a result of the merger on the relevant market. GSK’s acquisition of Novartis in 2015 raised concerns regarding cancer treatment drugs that were in both the late and early stages of product development. The acquisition by Novartis of drugs with the same action from GSK could result in Novartis ceasing to develop two early stage pipeline drugs. The drugs at the later stage of development, namely a skin and ovarian cancer treatment, were divested to their original developer to address the Commission’s concerns. However, the Commission also required that the drugs in early stage development continue along the path to commercialisation, which was achieved via a cooperation agreement with a third company.

In the same vein, the 2015 Pfizer/Hospira deal raised concerns regarding the development of two biosimilar drugs - one by each party to the transaction - that could treat certain auto-immune diseases, such as rheumatoid arthritis. As the
drugs were biosimilar (as opposed to generics), should both drugs have received further R&D, there was scope for differentiation strategies and non-price competition between the biosimilar products. The Commission accepted an undertaking to divest one of the biosimilar drugs to another company (Novartis) in order that both drugs were kept in the development process following the merger.

Before these cases, the Commission had only focused on late stage pharmaceutical products in undertaking an innovation analysis of a merger, (ie Phase III and IV test data).

And this change in the Commission’s approach was further exemplified in two other recent cases (both in 2017); the merger of: (a) Dow and DuPont and (b) Johnson & Johnson (J&J) and Actelion.

In March 2017, following a Phase II merger investigation, the merger between Dow and DuPont was conditionally approved by the Commission. The companies expected to save $3bn from efficiencies - $300m of which would stem from cuts to R&D.

As only five global players with R&D activity existed in the high-barrier to entry industry pre-merger, the Commission considered that the merger could remove the incentive to pursue parallel innovation efforts, leaving three players to compete with the merged entity post merger. However, the Commission raised the innovation theory of harm in an unprecedentedly wide and speculative context, noting that the cut to R&D would cause a reduction in other innovative pesticide products at some unspecified point in the future. The parties offered a package of commitments to address the Commission’s competition concerns, including divesting DuPont’s existing pesticide business and its global R&D organisation, with the exception of a few limited assets that support a part of DuPont's pesticide business.

On 09 June 2017, the Commission approved the acquisition of Actelion by J&J, on the condition that the different insomnia drugs being developed (phase II of development) by J&J and Actelion respectively were not delayed or discontinued as a consequence.

The Commission is increasingly looking beyond near-to-market pipeline products (ie those in phase III clinical trials) and focussing on products in phase I or phase II of development. In light of the fact that approximately only 11% of pharmaceutical products in the phase I development stage, and 30% of pharmaceutical products in the phase II development stage, make it to the next stage of development, this approach is arguably overly broad and intrusive.

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