Safeguarding the new

Mergers must not stifle innovation

*by **Miranda Cole****

The protection of innovation was a recurring theme in the European Commission's merger assessments in 2015. The competition commissioner noted the importance of innovation in merger review in her June 2015 state of the union address.

Legal framework

The legal framework for the assessment of the effect of concentrations on innovation is well established, and there are many earlier cases that turn on the issues. Both the horizontal and non-horizontal guidelines put the competition harm resulting from a reduction of innovation (with associated product quality and variety) on all fours with higher prices and lower output.

The horizontal guidelines provide that the Commission should intervene in the event that a concentration combines two important innovators, or eliminates an entity with promising pipeline products, so that the concentration hinders effective competition. The Commission takes into account the innovation potential of the parties to the concentration, regardless of their market positions prior to the concentration. As a result, there could be a competition problem even when an innovator has a limited market presence or has not yet entered the market. Issues with potential competition can arise if the potential entrant exerts a significant competitive constraint (or would be likely to do so over time) and there is otherwise insufficient potential competition.

Beyond this, the non-horizontal guidelines take a broadly similar approach to the assessment of the effect of a concentration on innovation. For example, they provide that, because vertical and conglomerate concentrations typically integrate complementary activities, they are more likely to create efficiencies than concentrations between competitors or potential competitors.

A changing approach

Of course, there are many older cases in which commitments have been offered to ensure innovation. In the life sciences sector, for example, remedies in a significant number of pharmaceutical and medical devices cases have related to late-stage pipeline products (for instance, products in Phase III clinical trials).

However, there has been a relatively recent shift in the review of issues related to innovation, and the breadth of divestitures and other commitments required to protect it. This appears to reflect a number of factors, including an appreciation that key decisions about certain development programmes may be made well before Phase III trials begin, and changes in market structures and behaviours as technology brings disruptive innovation and dynamic competition to new sectors.

While there were cases in 2014 and 2015 where the Commission required divestitures relating to markets in which one of the parties had a marketed product and the other a late stage development product (see Pfizer/Hospira and Medtronic/Covidien, for example), it also assessed the competitive effect much earlier in the pipeline in Novartis/ GlaxoSmithKline's Oncology Business.

The latter concentration raised concerns over innovation in the treatment of cancer, MEK and B-Raf inhibitors in particular. While both GSK and Novartis had ongoing Phase I and II clinical trials, one of Novartis's treatments was in Phase III. The Commission noted that, although pipeline products at early stages of clinical development face higher uncertainty as to their future clinical use than pipeline products at advanced stages of development, "the uncertainty about the outcome of ongoing clinical research does not preclude an assessment of the likely effects of the proposed transaction on the development of such pipeline products."

It went on to find that, given the more advanced stage of development of GSK's Mekinist and Tafinlar, "the competing clinical research programme for Novartis's MEK162 and LGX818 is instead likely to be deprioritised by the notifying party, resulting either in the abandonment or at least in a significant reduction of its current R&D efforts". Ultimately, the Commission concluded that the concentration:

> "[would] hinder innovation by significantly reducing the notifying party's incentive to develop the broader clinical research programme for LGX818 and MEK162, either as monotherapies or as combination therapies, for the various cancer types for which they are currently at early stages of clinical development and for potential further indications".

Novartis committed to divest its entire development programme for the two target molecules. The scope of the divestiture "essentially [consisted] of all rights, title, interests and assets necessary to continue developing and, if development is successful, commercialise MEK162 and LGX818". Novartis also committed to fund the development of its existing programme and carry out new clinical studies in the period prior to the divestment through "[entering] into transitional agreements and clinical trials agreements [which] ensure the continuation of the Columbus trials and other clinical trials involving MEK162 and LGX818".

While it is true that these development programmes were examples of oncology programmes focused on developing products for use against multiple types of cancer, rather than a particular form of the disease, it is still a much broader remedy than is usually required in remedies relating to pharmaceutical pipelines, both in that it related to the entire programmes and the particular programmes were early stage.

Covidien, Pfizer and Zimmer

A not dissimilar approach was also taken by the Commission in its 2014 review of the impact of the proposed concentration on the market for drug-coated balloon (DCB) devices in Covidien/Medtronic. While there were four market participants (so that three would have remained after closing), the Commission found that the proposed concentration would have removed the entity developing the next-generation product (ie Covidien).

The product in question was Stellarex, a DCB product in development that would compete, on launch, with Medtronic's

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In.Pact. The Commission found that "absent the transaction, Covidien would have continued to invest in developing the product and completing the trials" and that Covidien "[expected] to become the scientific leader and get ahead of Medtronic and Bard in the field of DCBs 166 and be the clear first choice [of] DCB … for customers". As the Commission put it:

> "[once] Medtronic acquires Covidien, it appears from Medtronic's internal planning that it is expected that the development of Covidien's product will be put to an end. This means that the transaction will … eliminat[e] a serious future competitor as a result of which DCB patients will be deprived of an innovative and potentially very effective device".

As a result, the proposed concentration was approved on the condition that Covidien divested its entire worldwide Stellarex programme (ie "research, development, manufacture, marketing, sale and distribution of Stellarex DCBs and a licence to the purchaser of certain PTA intellectual property currently owned by Covidien to operate that Stellarex DCB business").

Also in 2014, in Pfizer/Hospira, the Commission's focus was on the fact that the proposed concentration would lead to "two infliximab biosimilars [being] under the same ownership". Hospira had a marketed product, while Pfizer's pipeline biosimilar product was in Phase III. The Commission found that the merged entity would probably abandon the development of Pfizer's competing products, so that the proposed concentration would have "eliminat[ed] an important future competitive constraint".

As a result, the Commission required Pfizer to divest its full infliximab biosimilar development programme, including the manufacturing and marketing rights. The regulator was concerned that the commitments originally proposed by Pfizer were inappropriate to address the competitive concerns. It was particularly worried that the divestiture might lead to delays that would slow and potentially damage the development programme. As a result, it required Pfizer to revise its initial proposal to "avoid any delay" in the clinical trials and to "provide reasonable support" to the acquirer. Echoes of this concern and the Commission's solution are clear in the commitments that the Commission accepted in Novartis/ GlaxoSmithKline's Oncology Business.

In Zimmer/Biomet, the Commission considered the impact of the proposed concentration on the market for certain orthopaedic implants and related surgical products. It conditionally authorised the transaction, requiring Zimmer to divest a number of pipeline projects, characterising the remedies as "[ensuring] that patients continue to benefit from sufficient choice and innovation and that healthcare providers enjoy competitive prices".

A broader focus

This increasing scrutiny of the impact of concentrations on innovation is not limited to the life sciences sector. For example, a year ago, the agreement between Telenor and TeliaSonera to combine their Danish businesses in a joint venture elicited comments from Commissioner Vestager that she described as a "textbook reaction". Noting initially that the announcement had been interpreted as meaning that there would be less competition for Danish telecoms giant TDC, so that it would be able to "sit back" and "be less aggressive", she went on to say that "[it] is very telling for the fact that we need competition in order to get innovation, in order to get investment". The commissioner returned to this theme in her June 2015 Concurrence state of the union remarks, referring to the increased investment in the French mobile market that followed the 2009 entry of Free Mobile.

Illustrating the increasing breadth of the Commission's desire to protect innovation, it was concern over the impact on innovation that drove GE to undertake to dispose of Alstom's next generation large industrial gas-fired turbine technology, test sites and research and development engineers in GE/Alstom. The importance of innovation to the Commission's approach to that case was encapsulated by the commissioner: "Divestment of Alstom's key technology to produce heavy-duty gas turbines to Ansaldo will ensure that European business and consumers continue to benefit from this innovation and knowhow".

While the Commission has long focused its merger investigations in certain sectors on ensuring that concentrations do not stifle innovation, its recent practice represents a significant development in a number of key respects:

- The range of sectors in which the Commission focuses on protecting innovation appears to be broadening. This probably reflects a number of factors, including the extent to which technology is a key competitive feature and differentiator of products across an increasingly broad spread of sectors. Indeed, as the ongoing review of the Baker Hughes transaction also seems to show, this broadening appears to introduce an important dynamic into companies' assessment of transactions that might not have been there 10, or even five, years ago.
- Because it probably also reflects the growing importance of software, and the growth of competition between different software solutions, across the economy, this trend is likely to continue. For example, while air carriers have used backbone IT systems that interoperate with distribution IT systems for many years, the Commission had to consider the impact of a transaction on the growth of a disruptive alternative platform for the first time in its recent Amadues/Navitaire review.
- The breadth of commitments being sought has broadened materially. In addition to the cases in which the Commission has sought commitments relating to preclinical targets – and has addressed entire development programmes – the scope of the access remedy obtained from Intel (in Intel/MacAfee) can be viewed as enabling third parties to innovate on the Intel platform,
- It also appears to be an increasing focus of the regulator. Multiple speeches from the commissioner, director general and deputy director general for mergers does tend to send a message.

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