The importance of the new

Competition innovation in life sciences

*by **Ingrid Vandenborre****

Increasingly, EU merger control enforcement seems to be focused on the impact a proposed transaction is likely to have on innovation. This is reflected both in the EU Commission's substantive review of recent transactions, as well as its proposed legislative change to increase the EU Commission's jurisdiction over proposed transactions involving highly valued target companies with limited sales revenues. Both are particularly relevant to the pharmaceutical sector.

The Policy Brief

The EU Commission's April 2016 competition policy brief (the Policy Brief) refers to the horizontal merger guidelines (the Guidelines) that states that one of the effects to be analysed in merger control is the transaction's "effect on innovation", in addition to the transaction's effect on prices, output, or on the choice or quality of goods or services. The Guidelines state that a firm's "innovative potential" is to be taken into account, "regardless of current market position". Two main criteria are set out as determining the legal framework for the EU Commission's assessment. The first factor is whether the potential competitor is already or is significantly likely to become an effective competitive constraint. The second factor relates to the market structure. Notably, the EU Commission will take into account whether there are enough actual or potential competitors and whether there are significant barriers to entry that would impede other competitors from entering or expanding their market position.

The Policy Brief discusses several recent transactions where the EU Commission identified restrictions on innovation. It is notable that three out of the five examples discussed concern the life sciences sector, which is characterised by very significant level of R&D investment, increasingly through the acquisition of pipeline products. The Policy Brief notes that "innovation rivalry is a particularly important competitive factor in the pharmaceutical and medical device sectors and R&D is structured in such a way that it is possible at an early stage to identify competing products".

Medtronic, Novartis and Pfizer

In Medtronic/Covidien, Medtronic agreed to divest a late-stage pipeline product of Covidien as well as related assets that would enable a purchaser to bring the product to market, based on the finding that the relevant market was highly concentrated and Medtronic was the market leader. In Novartis/GSK Oncology, the EU Commission found that Novartis was likely to abandon its early stage clinical trial programmes for drugs that had the same method of action as those of GSK, and were therefore likely to result in duplicate clinical programmes. The transaction was approved on the condition that Novartis divest the two early-stage pipeline products with a commitment relating to the worldwide development of existing and new clinical studies. The third transaction discussed in the Policy Brief is the Pfizer/Hospira decision. The EU Commission identified an overlap between an existing Hospira biosimilar, and a biosimilar that Pfizer was developing. The EU Commission found that it was likely that Pfizer as a result of the transaction would have either delayed or abandoned development of the pharmaceutical (when there was only one other potential competing biosimilar identified), or licensed back the Hospira biosimilar to its co-marketing partner.

As reflected also in its Novartis/GSK Oncology decision, the Commission essentially takes three factors into account when defining the product market for pipeline products: general characteristics of the future product and the targeted therapy; the therapeutic indications of the product; and the product's stage of development. Further distinctions can be made based on the product's lines of treatment.

In this case, the notifying parties submitted that the type of cancer for which a pipeline oncology pharmaceutical is being developed is an appropriate starting point for market definition. They also noted that the future use of oncology pipeline pharmaceuticals, particularly targeted therapies, is likely to be determined by the indication for which they are undergoing Phase III clinical trials. In line with its previous decisions, in this case the Commission considered that when research and development activities are assessed in terms of importance for future markets, the product market definition can be left open, reflecting the intrinsic uncertainty in analysing products that do not exist as yet, and found that "the product market definition for pipeline pharmaceuticals can be guided primarily by the characteristics of future products as well as by the indications to which they are to be applied" (sections 17 and 18, 26 and 27).

Increasingly the EU Commission takes into account approved indications of clinical guidelines and lines of treatment. For example, the decision refers to the fact that respondents in the market investigation also indicated that "prescribers distinguish between different lines of treatment for targeted therapies […] and they generally follow the recommendation of the corresponding European clinical guidelines" (section 120).

The Commission's approach

The EU Commission distinguishes products in accordance with their phase of development. Phase III pipeline products are considered "close to entering the market". Moreover, in this decision, the EU Commission assessed competition in relation to the existing pipeline products, not solely their likelihood of ultimate launch. The parties had argued that Phase I and II products:

> "face considerable uncertainty as to their future clinical use and are not close to entering the market. The efficacy and safety of each product remains to be established. It is therefore difficult to predict in which disease or setting a pharmaceutical may ultimately be successful and it is far from certain whether the pharmaceutical will achieve the

* *Ingrid Vandenborre is a partner in Skadden Arps (Brussels)*

clinical results necessary to obtain marketing authorisation in the EEA" (section 99).

The EU Commission stated that "in a concentration involving pharmaceutical companies with competing clinical research programmes, it must be analysed whether after the transaction there will be a sufficient number of remaining clinical research programmes" (section 101).

The Commission summarised its methodology as follows: "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. However, 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. Whatever the level of uncertainty might be, a reduction in the efforts invested to bring forward a clinical research programme can reasonably be expected to reduce its probability of success. Ultimately, the abandonment of an entire clinical research programme for a certain product or products would have as [a] necessary consequence the failure in bringing such products to the market" (section108).

In this overall context, the likely success rate of the trials was taken into account. For example, based on information provided by the notifying parties, the Commission concluded that "in light of [...] regarding Bolero 1 and Bolero 3 clinical trials, it is very unlikely that Afinitor would be [...] approved in Europe, for the treatment of HER2+ advanced breast cancer" (section 182).

The EU Commission's assessment of pipeline products concerns potential competition, although the assessment of the existence of a "sufficient number of remaining clinical research programmes" suggests a broader analysis of innovation competition.

Assessing transactions

In other pharmaceutical transactions, the EU Commission has increasingly paid attention to the implications of a transaction on the merger parties' pipeline generally. A company often reassesses its pipeline and the priority projects when it acquires a new company with a new set of pipeline projects. Even if there is no direct competition between individual pipeline products, it would be reasonable for the merger firm to reprioritise the combined pipeline, with other projects of the acquired entity perhaps being considered as presenting greater opportunity when compared to the acquirer's existing set of pipeline products. This is often the case even in the absence of actual or potential competitive overlaps between the pipelines but on the basis of relative expenditures of different trials in comparison to their likely success rate. These assessments are often reflected in the documents reportable with the Form CO and are taken into account by the Commission.

This type of assessment requires an analysis not of the current market position of a company or a product, but what that position is likely to be in the future. It is not unlike the assessment the EU Commission has to undertake in determining the competitive relevance of a generic potential competitor in the context of a patent settlement agreement, even if the assessment there also concerns the legality of the patent and the product's non-infringing nature. The last example above underscores the need to establish competitive effects of the transaction that are merger-specific. It is likely that in any transaction, regardless of the specific target business involved, the buyer may revisit its pipeline valuation and priorities.

The EU Commission has tended to rely on two main sources of input for its assessment of the likely impact on innovation: the companies' internal documents and input from the merging parties' customers, competitors and even key opinion leaders (KOLs). Internal documents can be a difficult basis to assess expected success of R&D as different employees creating the internal material may have different views of the likely success of a product based on their own convictions, expertise and perhaps their role, responsibility and history with the company. An analysis based on internal documents also runs the risk that the review is insufficiently comprehensive, as some analysis may not have been put to paper, or may no longer be retrievable by the company.

New notification threshold

Last, as indicated above, the EU Commission – in line with the recent German merger control law changes – put up for consultation a proposal that entails the introduction of a new threshold for notification on the basis of which transactions that involve a certain transaction value, along with a local EU nexus, are subject to mandatory notification to and approval by the EU Commission, even if they do not meet the EU Merger Regulation notification thresholds. The new threshold was identified specifically to enable the Commission to review (among other things) acquisitions of pipeline compounds in the pharmaceutical sector, which currently tend to escape merger control review unless they form part of an existing business to which (sufficient) EU revenues can be attributed.

German approach

The EU Commission is not the only agency that identified an enforcement gap in this area.

The German Federal Ministry for Economic Affairs (BMWi) has already published its proposed amendment of the German restraints of competition legislation. The amendment provides that "the provisions on the control of concentrations shall also apply in cases where [...] the value of the consideration for the transaction is more than €350m [...]". Thus, future transactions will need to be notified in Germany if (1) the combined worldwide turnover of all companies exceeds €500m; (2) one of the parties to the transaction has a turnover in Germany of more than €25m; (3) the value of the consideration for the transaction exceeds €350m.

The new size of the transaction thresholds requires that the target "is active or is expected to become active in Germany". BMWi's explanatory note suggests that "expected to become" active would cover a timeframe of three to five years. That time period is potentially significant and may require companies to take into account pipeline product not yet in late-stage testing. A question also exists as to how transaction value will be calculated. According to the BMWi's explanatory note, the purchase price should be determined according to common M&A practice – ie as the sum of all monetary payments, transfers of voting rights, securities or tangible and intangible assets, and including payments subject to "earn-out" clauses.

These developments demonstrate the increasing importance of innovation competition in EU merger control review. They also open up a whole new set of challenges in ensuring that EU competition law can continue to support innovation.