United Kingdom

MERGERS

Decision—merger control—anticipated acquisition—pharmaceutical sector—separate phases of clinical trials—focus on pipeline products—possible divergence with EU's approach—material influence—frame of reference—unconditional clearance—international review of theories of harm in pharmaceutical transactions

Competition and Markets Authority; EU law; European Commission; Merger control; Pharmaceutical industry; Pharmaceuticals; Research and development

Early signs of divergence? The CMA's clearance decision in AstraZeneca's anticipated acquisition of Alexion

With the Brexit transition period having ended on 31 December 2020, the UK and EU are now distinct regulatory territories whose relationship is governed by the Trade and Cooperation Agreement. This means that the "one-stop" shop system established under the EU Merger Regulation (EUMR) no longer applies to the UK, and the UK's Competition and Markets Authority (CMA) is able to exercise jurisdiction to investigate transactions in parallel with the European Commission (EC). The CMA has been clear that there may occasionally be a need for divergence with other competition authorities, for example where market dynamics or applicable legal tests vary across jurisdictions.

On 14 July 2021, the CMA unconditionally cleared AstraZeneca Plc's anticipated acquisition of Alexion Pharmaceuticals, Inc. The CMA exercised jurisdiction over the transaction as Alexion's UK turnover exceeds £70 million. As part of its substantive assessment, the CMA considered whether the transaction would result in a loss of potential and dynamic competition in relation to the supply of certain products (which may be close competitors) for the treatment of a rare form of cancer. The CMA also assessed the impact of the transaction in relation to research and development (R&D) activities of the parties in relation to the complement system, a key part of the immune system.

The CMA's clearance decision recognises that the development of pharmaceutical products can be divided, at a high level, into three broad stages, namely, early R&D, clinical development—comprising sequential phases of trials (known as Phases I, II and III)—and obtaining regulatory approvals. However, the decision does not draw a distinction between products at different stages of the development cycle or separate phases of clinical trials, despite recognising that the success of products in clinical trials is a particularly important determinant of whether these products are authorised for eventual commercialisation. The decision is therefore interesting for a number of reasons, including its focus on early stage (Phase I and II) pharmaceutical products under development—typically referred to as pipeline products—which have been attracting far greater attention during merger investigations in recent years, and for being the first instance of a transaction in the pharmaceuticals sector to be investigated and cleared in parallel by the CMA and the EC, among other authorities.

Whilst the EC's clearance decision was not publicly available at the time of writing, the description on the EC's website suggests that the authorities may have diverged insofar as the EC's investigation appears to have focussed only on pipeline products at Phase II of clinical trials in the EEA. The divergence in the approaches adopted by the CMA and EC may, perhaps, be attributable to the nuances of each regime, including the material influence threshold in the UK, which in turn affects both the CMA's jurisdictional and substantive analyses.

Unlike the decisive influence threshold under the EUMR, the material influence threshold under the UK merger regime may be triggered by minority shareholdings, and the CMA typically assesses a number of factors in the round. In this case, the CMA found that AstraZeneca exercised material influence over an existing Chinese joint venture company—Dizal Pharmaceutical (Dizal). The CMA's conclusion was based on: (i) the scale of AstraZeneca's shareholding, which would allow it, in practice, to influence Dizal's management and its policy in the marketplace (including potentially blocking special resolutions); (ii) AstraZeneca's ability to appoint two of the

seven directors on Dizal's board; and (iii) AstraZeneca's significant pharmaceutical industry experience, which was expected to lead to its advice being followed to a greater extent than otherwise would be the case.

Having established that AstraZeneca exercised material influence over Dizal, the CMA identified another pipeline-to-pipeline overlap as relevant to its substantive assessment of the transaction. The additional overlap identified arose in the same space as the existing pipeline overlaps between AstraZeneca's and Alexion's products: for the treatment of Peripheral T-cell Lymphoma (PTCL). Whilst the CMA found AstraZeneca's investment in Dizal to be relevant for its substantive assessment of the transaction, it remains unclear whether any other authorities may have reached a similar conclusion.

Frame of reference

In line with the CMA's recent decisional practice and consistent with the evidence provided by the parties, the CMA relied on product indications and the areas of the parties' overlapping activities as the start point for its analysis.

On that basis, the CMA assessed the supply of products for the treatment of relapse/refractory PTCL patients without further segmentation. For the geographic scope, the parties' position was that the appropriate frame of reference would be global, as the products were at an early stage of clinical trials and any commercialisation considerations would be carried out at a global level. The CMA acknowledged that certain competitive parameters relevant to pipeline products, such as product quality and innovation, would likely be set on a global basis. However, as suppliers primarily compete on price when a product is ultimately marketed (and local competitive conditions typically influence competition on price), the CMA's conclusion was that the frame of reference should be national in scope. This conclusion reflected a number of additional factors, including national regulatory schemes for authorising and reimbursing treatments.

As several products for treatment of PTCL were under development and expected to be available in the foreseeable future, the CMA adopted a forward-looking approach and did not limit its assessment to marketed products alone. Thus, the CMA considered the impact of the transaction on the treatment of relapse/refractory PTCL patients in the UK, taking account in its competitive assessment the constraint of products in development globally, including products which may not be aimed at being marketed in the UK.

In regard to the other overlap between the parties (i.e. in their R&D activities for the complement system), the CMA considered a frame of reference that comprised the development of products targeting the complement system, which may ultimately treat a wide range of possible indications. In doing so, the CMA recognised that in some cases—in line with its current *Merger Assessment Guidelines*—there may be a broader pattern of dynamic competition in which the specific overlaps may not be identified easily at the point in time of the CMA's assessment. Further, as the CMA has acknowledged that certain competitive parameters, including R&D and innovation, are likely to be relevant on a global basis, the CMA assessed the impact of the transaction on the development of products targeting the complement system globally.

Conclusion

The CMA concluded in this case that the merged entity would face sufficient competitive constraints from several alternative suppliers of products post-transaction in respect of both overlaps. The transaction therefore did not give rise to a realistic prospect of a substantial lessening of competition

as a result of horizontal unilateral effects. The decision is a helpful precedent of the CMA's likely approach post-Brexit to assessing pharmaceutical transactions involving early stage pipeline products.

However, the CMA has recently joined an international working group tasked with reviewing and updating the way in which pharmaceutical mergers are analysed and assessed by competition authorities. The other members of the working group are the EC, the US Federal Trade Commission, the Department of Justice, the Offices of State Attorneys General, and the Canadian Competition Bureau. The working group is considering, among other things, the relevant theories of harm for pharmaceutical merger investigations and the approach to market definition, particularly in the context of new or evolving theories of harm. It is therefore entirely possible that the CMA's decisional practice in this area might evolve further.

Alex Nourry
Partner, *Clifford Chance LLP*

Deepaloke Chatterjee
Associate, *Clifford Chance LLP*