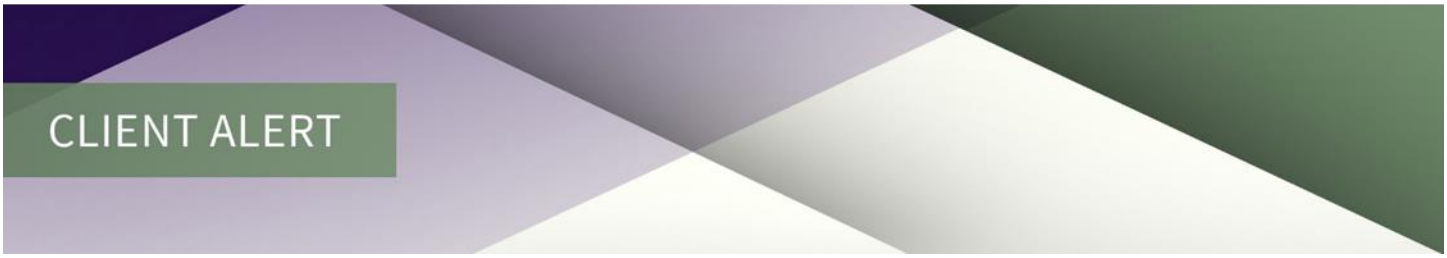

CMA Merger Review in Roche/Spark Signals More Interventionist Approach

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On 10 February 2020, the UK Competition and Markets Authority (***CMA***) published its clearance decision concerning the acquisition by Swiss-headquartered biotechnology firm Roche Holdings, Inc. (***Roche***) of Spark Therapeutics (***Spark***). Roche manufactures Hemlibra, a drug to treat congenital Haemophilia A (***Hem A***), and Spark is currently developing two Hem A gene therapy (***GT***) products.

The CMA investigated the deal, which the parties had not voluntarily notified, on the basis that the CMA's jurisdictional "share of supply" test was met. The CMA concluded that the test was met even though US-based Spark had generated no sales in the UK and its Hem A products remained in development and were therefore not currently being marketed anywhere in the world.

Roche and Spark are unlikely to challenge the CMA's approach, as the CMA has cleared the deal unconditionally at Phase I. However, parties to future deals should take heed. The CMA's decision to assert jurisdiction to review the acquisition of a target business which had no sales in the UK could foreshadow a significantly more expansive approach to "calling in" non-notified mergers for review.

Background

On 25 February 2019 Roche and Spark (the ***Parties***) announced their $4.3 billion tie-up, which they notified to the US Federal Trade Commission (***FTC***) one week later. The Parties did not voluntarily notify the deal, which did not qualify for the European Commission's "one-stop shop" review, in the UK. However, the CMA's mergers intelligence unit closely tracks merger activity. In June 2019, following a "second request" from the FTC, the CMA imposed an initial enforcement order (***IEO***) on the Parties to prohibit the integration of their businesses, pending the CMA's review.

The Parties took issue with this measure, arguing that the CMA lacked jurisdiction to review the deal, as Spark was not active in the supply of *any* products in the UK.

Contested jurisdiction

In order for the CMA to have jurisdiction to review a merger, one of the following two tests must be met:

(i) the value of sales of the target business which were generated in the UK must exceed £70 million in the last financial year (the ***Turnover Test***); or

(ii) the merger parties' combined share of supply of goods or services must be 25% or more in the UK or any substantial part of it (the ***Share of Supply Test***).

Importantly, in order for the Share of Supply Test to be met, the merger must also result in an increment to the combined share of supply. The Share of Supply Test cannot be met by one party's share of supply alone.

In response to the Parties' arguments, the CMA acknowledged that the Turnover Test was plainly not met, as Spark had generated no revenues in the UK. However, the Share of Supply Test *was* met because Roche and Spark overlapped in the supply of novel non-GT and GT Hem A treatments in the UK and:

- Roche and Spark employed more than 25% of workers employed in the UK who are engaged in activities related to novel non-GT and GT Hem A treatments in the UK; and
- Roche and Spark procured more than 25% of UK patents for the treatment of Hem A.

CMA's general guidance on the Share of Supply Test

In its published guidance, the CMA states that it has wide discretion in describing the relevant goods or services, so long as the description is reasonable and the parties' share of supply on that description is 25% or more. The CMA also indicates that the share of supply need not amount to a relevant economic market and that goods or services are deemed to be "supplied" in the UK if customers are located in the UK.

In its *Roche/Spark* decision, the CMA builds on such guidance, describing the Share of Supply Test as a "key gateway" to providing the CMA with the power to intervene in deals that may raise competition concerns that could impact UK consumers. The CMA proves willing to assert jurisdiction in acquisitions of targets which have *no UK revenues* and otherwise make *no market-facing supplies* to customers yet.

Application in *Roche/Spark* and rejection of the Parties' defences

The Parties disputed the CMA's jurisdiction for three reasons:

1. Spark was not active in the supply of Hem A products in the UK;
2. the CMA's description of goods under the Share of Supply Test was not reasonable; and
3. in any event, the threshold under the Share of Supply Test (25%) was not met.

The CMA rejected each of these submissions.

1. Finding that Spark is active in the supply of novel GT and non-GT Hem A treatments

The Parties submitted that Spark did not supply any marketed Hem A products and that the CMA does not have jurisdiction to review mergers on the basis of a *prospective* assessment that a merger may potentially meet the Share of Supply Test in future.

The CMA rejected the Parties' submission on the basis that, in determining the scope of "supply," the CMA must take into account the commercial realities of the sector at issue. In relation to the pharmaceutical sector, the CMA considered that such realities included the multiple stages of R&D and clinical trials which precede market authorisation for a treatment.

The CMA found that the evidence before it indicated that companies with *existing* products on the market alter their commercial strategies in order to compete with pipeline products, both before and after commercialisation, even in the R&D stages of development.

The CMA concluded that because Spark was engaged in R&D activities relating to Hem A treatments, Spark should be considered as active in the "process of supplying" the treatments, *even if Spark had made no actual sales of its treatment in the UK.* In the CMA's view, Spark's "supply" had a UK nexus because (i) Spark's R&D activities, though carried out globally, were integral to making the treatment available in the UK; and (ii) Spark had obtained various UK/EU patents relating to the treatment of Hem A and employed persons responsible for its commercialisation in the UK.

2. Reasonable description of goods

As noted above, the CMA found that the Parties overlapped in the supply of novel non-GT and GT Hem A treatments in the UK (including commercialised and pipeline treatments which are, at least, at Phase II stage of clinical development). This description of goods excluded traditional non-GT treatments. In the CMA's view, it was reasonable to exclude such treatments because the CMA considered that they may have significant disadvantages relative to novel non-GT

treatments (such as Roche's Hemlibra) and to novel GT treatments (such as Spark's pipeline product), which the CMA expected to compete more closely with each other than with traditional non-GT treatments.

The CMA then considered whether basing the relevant description on novel non-GT and GT pipeline treatments that are at Phase II (or more advanced stages) of clinical development was reasonable. The CMA concluded that including pipeline products was justified because market players considered such products to have a realistic potential of successful commercialisation. The Parties submitted that the CMA's approach departed from the CMA's decisional practice, which focussed on a narrower market.[1] The CMA considered the relevance of earlier decisions to be limited due to (i) more recent industry developments and (ii) the particular segments at issue, which had not included novel non-GT and novel GT treatments.

The CMA also noted that the CMA's description of goods need not amount to a relevant economic market, such that a *substantive* assessment in an earlier decision has limited relevance to *jurisdiction*.

3. At least a 25% share of the supply

The Parties submitted that even if the CMA were to adopt the description of goods comprising all actual and potential non-GT and GT treatments, the threshold under the Share of Supply Test would not be met, as Roche had supplied less than 5% of UK patients diagnosed with Hem A in 2017/18.

The CMA rejected this submission, noting that the relevant UK legislation gives the CMA the discretion to choose such criterion (*e.g.*, value, cost, price, quantity, capacity, number of workers employed or some other criterion) or combination of criteria as the CMA considers appropriate.

The CMA concluded that the Share of Supply Test was met on the basis of (i) the proportion of workers employed in the UK to undertake activities related to novel non-GT and GT Hem A treatments in the UK and (ii) the proportion of patents procured for the treatment of Hem A.

Key takeaways from *Roche/Spark* looking ahead

The CMA's decision in *Roche/Spark* provides a cautionary reminder for merger parties to consider carefully the existence of a possible UK nexus and overlap (even on what might appear *prima facie* to be quite far-fetched reference segments) before deciding not to voluntarily notify a deal to the CMA. A later intervention by the CMA can risk significant delays to the deal timetable and may result in additional costs to the merger parties, who might be required to hold the target business separate, pending the CMA's assessment.

[1] Paragraph 100, referring to ME/6711/17 *Completed acquisition by Tiancheng International Investment Limited (part of Creat Group Co., Ltd.) of Biotest AG* (decision of 15 May 2018).

The CMA's intervention in *Roche/Spark* lasted six months, even though the CMA ultimately cleared the deal unconditionally in Phase I. A deal that could raise significant competition issues might face an even longer delay. More than a year after the parties signed the deal, the CMA's intervention in *Sabre/Farelogix* is still ongoing.

The CMA's approach to jurisdiction in *Roche/Spark* also forms part of a wider group of non-notified mergers which have been "called in" by the CMA. In August 2019, Sabre disputed the CMA's conclusion that the supply of services to British Airways alone – rather than to a wider set of airlines – was a reasonable description of services on which to calculate the merger parties' share of supply.[2] The CMA disagreed. It considered that certain characteristics distinguished British Airways from all other airlines in the UK. In a sub-segment which contained only a *single* customer, the Share of Supply Test was met.

In several other cases which were called in by the CMA, only one party had market-facing activities in the UK. In February 2020, the CMA imposed an IEO to prohibit the integration of Just Eat and Takeaway.com, even though Takeaway.com has ceased its operations in the UK. Earlier, in July 2019, the CMA imposed an IEO in relation to Amazon's minority investment in Deliveroo. Amazon exited the UK as a supplier of online food delivery services in November 2018, but the CMA is concerned that the deal could damage competition in online restaurant food delivery by discouraging Amazon from *re-entering* the UK market.

In *Amazon/Deliveroo* and, if the CMA proceeds to investigate *Takeaway.com/Just Eat*, the Turnover Test will be met (as both Deliveroo and Just Eat generate more than £70 million UK turnover), and so the CMA does not need to rely on the Share of Supply Test. However, the decision to investigate the deals, together with the expansive approach to the Share of Supply Test in *Roche/Spark* and *Sabre/Farelogix*, is a clear indicator that the CMA will carefully analyse transactions on a dynamic, forward-looking basis, even in cases where parties may be only potential, and not actual, competitors in the UK.

[2] Case ME/6806/19 *Anticipated acquisition by Sabre Corporation of Farelogix Inc* (decision of 16 August 2019), paragraphs 90 and 110. The CMA considered the fact that more than [70-80]% of British Airways' bookings were made via the three largest Global Distribution Systems (***GDS***) an indicator that British Airways' bookings represent a substantial portion of all bookings made with UK airlines through such GDSs. The CMA also considered that the Share of Supply Test was met with regard to the supply of services that facilitate the indirect distribution of airline content to travel agents in the UK (para 140).

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