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RESEARCH & DEVELOPMENT – BEWARE OF THE LONG REACH OF THE UK COMPETITION AND MARKETS AUTHORITY'S JURISDICTIONAL ARM

To Our Clients and Friends:

The recent case of Roche/Spark[1], in which Gibson Dunn acted for Spark, shows that the UK Competition and Markets Authority (the "***CMA***") is willing to intervene in transactions on the basis of a company's R&D efforts alone, i.e. in the absence of a commercialised product. This case is particularly relevant to pharmaceutical companies. It also has potentially wider implications for other markets where R&D is an integral part of the supply process.

In Roche/Spark, the CMA found that it had jurisdiction to review the USD 4.3 billion transaction based on the fact that Roche (the acquirer) was *marketing* products in the UK in the area of haemophilia A treatments and Spark (the target) was active in the *clinical development* of gene technology ("***GT***") treatments for haemophilia A.

The basis for establishing jurisdiction was the 'UK share of supply test', which requires that both parties be active in an overlapping area of supply in the UK. The CMA for this purpose concluded that a firm *engaged in R&D activities* relating to haemophilia A treatments in the UK (in particular activities at a 'relatively advanced staged', meaning Phase II or more of clinical development) is *active in the process of 'supplying' such pharmaceutical treatments* in the UK.

It is also of interest that the vast majority of Spark's activities were found to take place abroad and all of its 'UK' activities fell within the context of a global R&D programme. Regardless, the CMA still found sufficient UK nexus to review the transaction, based on limited factors, including future UK links.

This decision highlights the increasingly interventionist approach that the CMA is taking with respect to M&A activity in sectors where innovation is important - the CMA being particularly alert to the possibility of so called 'killer acquisitions' in these areas.

The approach adopted in this case is consistent with statements made by the CEO of the CMA previously, that the CMA will use the share of supply test flexibly in innovative markets in order to investigate the rationale behind a high target valuation: "*In relation to jurisdiction, […] we can also consider the parties' combined share of supply, and exercise jurisdiction if this exceeds 25% and any kind of increment in share is brought about by the deal. This is a flexible test which, in practice, has meant that the CMA has consistently been able to exert jurisdiction over transactions in digital markets, for example where the turnover of the target was limited, but the value of the deal was high*" (emphasis added).

The same speech also signalled an interest in reviewing high-value deals for potential "killer acquisition" effects, noting that: "*if the price paid by the acquirer seems hard to explain based on current or likely future earnings, we should scrutinise the rationale for the acquisition with particular rigour and consider, in particular, whether the purchase price could reflect the benefit of killing off emerging competition*."[2]

The Roche/Spark decision provides a practical demonstration of how the CMA may seek to establish jurisdiction in these cases.[3] It also provides a timely reminder that, going forwards, parties need to be wary of the jurisdictional approach of the CMA when transacting in innovative markets. The rationale and basis for establishing jurisdiction in this particular case is further described below. We have also outlined, at the end of this briefing, some considerations for current and future transactions based on this decision.

Jurisdictional Approach in Roche/Spark – the UK Share of Supply Test

The CMA's decision to review the Roche/Spark transaction was based on a wide interpretation of the share of supply test and full use of its discretion when applying this test. In particular, the CMA found that the statutory definition of 'supply' is broad enough that it does not require actual sales.

Approach to the concept of 'active in the supply' of a pharmaceutical treatment

Spark was found to be 'active in the supply of haemophilia A treatments in the UK', despite the fact that its products were still in clinical development and have not yet been put on the market.

The CMA's conclusion was based on an expansive interpretation of the competitive process. The CMA relied on the fact that the supply of a product in the pharmaceuticals sector encompasses several stages, with the R&D stage being an integral part of the process of supplying pharmaceutical treatments. The CMA then said that it found evidence showing that 'significant competition' exists between firms before their products are fully commercialized. That is, a firm with a currently-marketed product will alter its commercial strategy to compete against a product that is still in (albeit at a relatively developed stage of) clinical development and *vice versa*. This conclusion seems largely based on broad principles concerning the characteristics of pharmaceutical markets,[4] with only limited high-level examples given in the decision of the type of evidence actually relied on.[5] On this basis, the CMA found that its jurisdictional assessment could extend beyond a consideration of already marketed products, in order to reflect the commercial realities by which companies in this area interact.

A similar approach could be followed in future pharmaceuticals transactions, as well as in other sectors where R&D is an integral part of the process, particularly if there is some transparency as to competitors' pipeline product development efforts and some evidence of competitive response.

UK nexus established based on minimal activities in the context of a global R&D programme

The CMA's finding that Spark was active in the supply of GT haemophilia A treatments *in the UK*, was similarly based on a wide view of what is required for a UK nexus.

As the CMA accepted, most of Spark's activities took place abroad: "*[m]ost of Spark's current Hem A R&D activities are carried out in Philadelphia, where Spark's laboratory space and R&D professionals dedicated to SPK-8011 and SPK-8016 are located. Spark's clinical trials for SPK-8011 and SPK-8016 are also managed from Spark's Philadelphia-based operations. Of Spark's eleven open clinical trial sites for SPK-8011, two are outside of the United States.*"

Nonetheless, the CMA found a UK nexus based on the fact that R&D activities form an integral part of the process of making treatments available in the UK, and that several of Spark's activities relevant to R&D and/or intended commercialisation took place in the UK – namely, Spark held certain UK/EU patents, had some employees undertaking activities in the UK and intended to include UK sites in clinical trials.

A UK nexus was thus established based on what can only be understood as minimal UK-based activities compared to Spark's global R&D platform, together with future intentions as to (a) making treatments (if successfully developed) available in the UK and (b) conducting future clinical trials in the UK.

Frame of reference and measures for assessing the 25% threshold

In measuring whether the 25% share of supply test was met, the CMA looked at activities relating to the supply of 'novel non-GT and GT haemophilia A treatments (including commercialised treatments and pipeline treatments which are at the Phase II or more advanced stage of clinical development)' and used the specific metrics of (a) the number of full-time equivalent UK-based employees engaged in such activities; and (b) the 'procurement' of UK patents[6].

As a preliminary point, it is worth noting that the CMA's focus on "novel" treatments, to the exclusion of the many traditional haemophilia A treatments, made it far more likely that the share of supply test would be met in this case.[7] Future cases involving innovative companies may also see a similarly narrow focus at the jurisdictional stage.

The second point to note is that the CMA relied on somewhat opaque and difficult to measure metrics in this case, which may prove a challenge for companies to replicate when considering whether to notify future deals.

In particular, in terms of the methodology adopted for calculating the shares, the CMA stated in its decision that a 'simple quantitative counting exercise' had been conducted (with no consideration of qualitative differences between employee or patent units). However, counting patents is well recognised to not be a straightforward exercise and the exact scope of employee activities taken into account was not explained.

Further, the calculations performed by the CMA in this case were based on data collected directly from various industry players. Transacting parties are likely to find it difficult to estimate internally an equivalent when their deal involves R&D. For example, information on the number of employees working on project pipelines or other R&D tasks are confidential. One cannot necessarily make inferences based on a merging party's own set up, as there is no particular reason why a competitor would follow a similar approach in the UK in order to compete effectively in this area.

Finally, it is interesting that the metrics relied on by the CMA have only an indirect link to the ultimate substantive assessment. Metrics concerning the number of patents granted and straight counts of UK-based employees have little relation to the likely success and competitive impact of the ultimately-developed products or even to any qualitative assessment of the extent and strength of current R&D activities.

What does this decision mean for current and future transactions?

This decision signals very clearly that the CMA's jurisdictional thresholds are viewed by the CMA as a technical barrier to overcome in cases where the CMA wishes to investigate the potential effects of a merger or acquisition.

For companies active in industries where competition exists between firms before their products are fully commercialised (stimulated by transparency in R&D activities) or where R&D is an integral part of the supply process, it is clear that the absence of target turnover in the UK or overlaps in directly marketed products or services will not be a bar to the CMA seeking to take jurisdiction.

Consequently, in such industries (and particularly in the pharmaceuticals sector) going forward, the possibility of UK CMA intervention must be considered even where one or both of the parties do not have UK turnover, if the parties' actual and potential or potential products (as applicable) can be categorised within the same category of products. The risk of CMA intervention is likely to increase the further along the development process a pipeline product is and where there is evidence that the potential treatment/product is intended be marketed in the UK and/or activities are taking place in the UK with respect to the relevant product.

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[1] ME/6831/19 - *Anticipated acquisition by Roche Holdings, Inc. of Spark Therapeutics, Inc*. See full decision here: https://assets.publishing.service.gov.uk/media/5e3d7c0240f0b6090c63abc8/2020207_-_Roche_Spark_-_non-confidential_Redacted-.pdf

[2] See the full version of Andrea Coscelli's speech to the OECD/G7 conference on competition and the digital economy in June 2019 here: https://www.gov.uk/government/speeches/competition-in-the-digital-age-reflecting-on-digital-merger-investigations.

[3] Another recent example of the CMA taking steps to investigate a merger where one party has no market facing activities in the UK includes the CMA's decision to investigate the acquisition by Takeaway.com, a leading online food delivery marketplace in Continental Europe, of Just Eat, one of the main players in the UK food delivery marketplace.

[4] Specifically, it states that many pharmaceuticals markets are characterized by: (i) significant switching costs (in particular, because patients may be highly reluctant to switch treatments) which it felt meant that, in practice, incumbent firms have an incentive to compete against known pipeline products so as to win as many patients as possible before such products come to market and reduce the

eventual impact of such products on coming to market; and (ii) a degree of transparency meaning that pipeline product development can be tracked.

[5] The evidence of competitive interactions relied on (based on the un-redacted text) includes evidence showing that: (i) global marketing efforts, efforts to establish a strong presence in the haemophilia community and efforts to encourage stronger rates of uptake for marketed products are 'in part' a competitive reaction to pipeline products; (ii) third parties closely monitor the treatment pipeline and track the development of individual pipeline products (competitors, clinicians and haematologists); and (iii) companies active in R&D invest in promotion activities prior to products being commercialized, to ensure brand recognition before products come to market.

[6] Including EU patents validated in the UK.

[7] The CMA distinguished: (i) *traditional non-GT* from *novel non-GT and GT* haemophilia A treatments for this purpose; and (ii) pipeline treatments at Phase II (or more advanced) stage of clinical development from pipeline treatments at Phase I stage of clinical development (or earlier). Notably, the CMA went on to assess the impact of the merger in relation to the supply of all haemophilia A prophylactic treatments, including traditional FVIII treatments.

The following Gibson Dunn lawyers assisted in preparing this client update: Ali Nikpay, Deirdre Taylor and Sarah Parker, who represented Spark before the UK CMA. Adam di Vincenzo and Richard Parker secured clearance for the deal from the US Federal Trade Commission.

Gibson Dunn's lawyers are available to assist in addressing any questions that you may have regarding the issues discussed in this update. For further information, please contact the Gibson Dunn Lawyer with whom you work, any member of the firm's Antitrust & Competition practice group, or the authors:

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