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Biopharma Mergers Remain in Global Antitrust Spotlight

Abandoned Illumina/Pacific Biosciences Merger Exemplifies Increased Scrutiny in US and UK

SUMMARY

On January 2, 2020, Illumina, Inc. ("**Illumina**") and Pacific Biosciences of California, Inc. ("**PacBio**") abandoned their proposed $1.2 billion merger following antitrust probes by the Competition and Markets Authority (the "**CMA**") in the United Kingdom and the Federal Trade Commission (the "**FTC**") in the United States. The antitrust enforcers articulated serious concerns about the transaction's effects on competition in the global market for DNA-sequencing systems.

This scenario highlights the ongoing – and perhaps escalating – antitrust scrutiny that companies in the biopharmaceutical and technology sectors are facing across jurisdictions. The case exemplifies the regulators' increased attention to the preservation of nascent competition and comes on the heels of statements by authorities on both sides of the Atlantic that "the elimination of even a very small or nascent competitor could remove an important source of competition." The Illumina/PacBio combination demonstrates both the CMA's and FTC's willingness to scrutinize acquisitions by established competitors of smaller players still in the development phase – especially in the biopharmaceutical sector.

THE TRANSACTION

On November 1, 2018, Illumina agreed to acquire PacBio for $1.2 billion. Both companies are US-based DNA sequencing providers that conduct business globally, though their respective products are meaningfully differentiated in capabilities and end use. The CMA initiated a merger inquiry into the proposed transaction on April 18, 2019 *ex officio*, asserting jurisdiction solely on the basis of the miniscule increment of share of supply of DNA sequencing systems that Illumina would gain as a result of its acquisition of PacBio (0%-5%). On January 2, 2019 the FTC issued second requests to the two companies, thereby initiating a full phase investigation of the transaction. Likewise, on June 27, 2019, the CMA launched an in-depth (Phase 2) investigation into the proposed merger. Originally, the parties

intended to consummate the merger mid-2019. Amid ongoing antitrust scrutiny from both sides of the Atlantic, however, on September 25, 2019 the Parties amended the merger agreement to, among other things, extend the end date to December 31, 2019, subject to Illumina's unilateral right to extend the end date until March 31, 2020. On December 18, 2019, Illumina exercised that right and extended the end date to March 31, 2020.

On October 24, 2019, the CMA published the provisional findings of its Phase 2 investigation, concluding that the merger would likely result in a significant loss of competition in the highly concentrated DNA sequencing industry. The CMA went on to say that the elimination of an innovative competitor such as PacBio could have a particularly critical impact on competition by harming innovation. In the hope of addressing the CMA's concerns, Illumina twice offered remedies consisting of licensing of various patents associated with the companies' DNA sequencing systems. However, in its provisional findings, the CMA found that there would be no remedies short of prohibition that could adequately address the competition concerns raised by the transaction.

Nearly two months later, the FTC reached a conclusion consistent with that of the CMA. On December 17, 2019, the FTC voted unanimously to challenge the proposed acquisition in an administrative tribunal, alleging that Illumina was attempting to unlawfully maintain a monopoly over next-generation DNA sequencing systems in the US and that the merger would eliminate a "nascent competitive threat." Because the parties did not immediately close the transaction due to the ongoing UK review, the FTC did not have to adhere to its usual process of simultaneously filing to halt the merger in Federal court. Like the CMA, the FTC's complaint emphasized the critical role that competition plays in promoting innovation in the pharmaceutical industry, and alleged that "PacBio and Illumina drive each other's innovation and the acquisition would eliminate that incentive."

Against the backdrop of mounting challenges from these regulators, the parties elected to terminate the proposed transaction on January 2, 2020. Although the parties agreed to use their reasonable best efforts to obtain clearance, Illumina was not required to negotiate or agree to any divestitures in order to secure regulatory approval under the terms of the merger agreement. Illumina will now pay PacBio a $98 million termination fee.

ANALYSIS

Increased scrutiny of pharma deals

This case is the latest in a series of FTC investigations that evince increased attention to the competitive implications of an incumbent firm acquiring a so-called "nascent" competitor. Pursuit of an enforcement action when a nascent competitor is being acquired requires the FTC to conduct a somewhat more challenging, nuanced analysis than a case in which two firms already compete directly pre-merger. Yet, the agency's recent enforcement activity demonstrates that it is not afraid to pursue a "nascent competitor" theory of harm and, in fact, may be increasing its competency and focus in this area. At a 2018 speaking engagement, FTC Chairman Joe Simons addressed the issue and declared the FTC's intention to dedicate resources to the thorny questions implicated by "high-tech platforms and nascent competitors." He explained that "[t]hese types of transactions are particularly difficult for antitrust

enforcers to deal with because the acquired firm is, by definition, not a full-fledged competitor, and the likely level of future competition with the acquiring firm often is not apparent. But the harm to competition can nonetheless be significant."

The FTC's challenge to the Illumina/PacBio transaction brought the Chairman's remarks to life. In this case, the merging parties were not head-to-head competitors at the time of the merger. To the contrary, the FTC acknowledged that Illumina and PacBio's DNA sequencing systems were highly differentiated. Illumina provides short-read DNA sequencing systems and PacBio provides long-read systems – two technologies with different benefits, costs, accuracy and throughput rates. Still, the FTC was concerned that PacBio's long-read sequencing technology was on course to improve in accuracy and drop in price, causing the markets to converge into a single competitive arena in the near future. According to the FTC, but for the merger, improvements to PacBio's technology would position the company as a direct rival to Illumina's longstanding dominance in the DNA sequencing space. Finally, customers would have a strong substitute for Illumina, and thus, pricing leverage. While more remote and attenuated than a traditional enforcement action against currently competing firms, this nascent competition theory was sufficient basis for the FTC to mount a challenge to the proposed Illumina/PacBio merger. As FTC Deputy Director Gail Levine explained, "[w]hen a monopolist buys a potential rival, it can harm competition. These deals help monopolists maintain power. That's why we're challenging the acquisition."

The FTC's handling of Bristol-Myers Squibb's ("**BMS**") recent acquisition of Celgene also portends increased agency scrutiny of biopharmaceutical transactions. In this case, the FTC alleged that BMS's pipeline product for treatment of psoriasis would soon enter the US market for treatments taken orally for moderate-to-severe psoriasis. As such, it would become a direct competitor to Celgene's on-market psoriasis drug, Otezla. Although the FTC ultimately approved the transaction subject to the $13.4 billion divestiture of Otezla (which is the largest divestiture that either the FTC or the United States Department of Justice has ever required in a merger enforcement action), the approval was non-unanimous and was split on strict party lines. In separate dissenting opinions, Commissioners Slaughter and Chopra questioned whether the FTC's historical approach to pharmaceutical mergers, in which it evaluates and tailors remedies to drug-level overlaps, has resulted in underenforcement. Both dissenting Commissioners suggested that the time has come for the FTC to adopt a more expansive approach to analyzing the competitive consequences of pharmaceutical mergers. They did not offer details about what a more expansive approach would entail.

The CMA has been following a similar approach to biopharma deals. The CMA reinforced its determination to enhance scrutiny in the pharmaceutical sector in its 2017/2018 Annual Report, where it stated that the CMA is "willing to pursue big cases through which we have the potential to deliver significant benefit for consumers, taxpayers and the economy generally, and where necessary or appropriate to set important precedents for the future." In his foreword to the 2018/2019 Annual Report, CMA Chief Executive Dr. Andrea Coscelli affirmed that "enforcement in the pharmaceutical sector has been a priority for [the CMA] for several years."

In parallel with its review of Illumina/PacBio, the CMA recently reviewed (and subsequently cleared), *ex officio*, the merger of Roche Holdings, Inc. ("**Roche**") and Spark Therapeutics, Inc. ("**Spark**"). Both Roche and Spark develop treatments that aim to prevent bleeding in patients with Hemophilia A. Like the target in Illumina/PacBio, however, Spark does not yet commercialize any products competing with Roche's "Hemlibra" drug, but is currently only in the process of developing a gene therapy treatment, expected to compete Hemlibra in the future. On June 11, 2019, consistent with its established practice, the CMA issued an initial enforcement order, preventing the parties from integrating the two businesses, transferring the ownership or control of the Roche and Spark businesses or any of their subsidiaries, or otherwise impairing the ability of Roche and Spark to compete independently. The CMA formally launched its merger inquiry on October 22, 2019. On December 16, 2019, the CMA cleared the Roche/Spark combination on the basis that Spark would not be the only supplier developing a gene therapy treatment for Hemophilia A, and that Spark's pipeline product could not be considered to have any particular advantages over those developed by other companies.

Similarly to the developments in the US, the CMA's enhanced review of biopharma deals comes only shortly after, and dovetails with, its announcement of an increased level of scrutiny of technology mergers. On June 3, 2019, in a speech to the OECD/G7 conference on competition and the digital economy, Dr. Coscelli stated that "the elimination of even a very small or nascent competitor could remove an important source of competition. In such markets, it could be that any entrant with a credible strategy and route to funding is worth protecting." Dr. Coscelli echoed the FTC's comments on potential underenforcement in this area and advocated in favor of broadening the merger review "to accept more uncertainty in their assessment of the counterfactual," by reviewing a merger not only with reference to current competitive conditions and "near-term market developments," but by considering the long-term future development of the firms involved. The CMA's review and findings in both Illumina/PacBio and Roche/Spark are in line with this approach, which follows the trend set by the European Commission in its decisions in cases like Dow/DuPont and Bayer/Monsanto, rendering innovation competition a critical focal point of EU merger reviews.

CMA continues to assert broad jurisdiction over non-UK mergers

The CMA's provisional findings in Illumina/PacBio are remarkable in the fact that they culminated in a provisional finding of prohibition, and the parties subsequently abandoning the deal, notwithstanding the transaction's very weak jurisdictional link to the UK. The following two aspects are of particular note.

First, the case illustrates that a transaction may trigger a CMA review even if the parties' presence in the UK is limited or even insignificant. The CMA's provisional findings are a clear illustration of Dr. Coscelli's remarks at the OECD/G7 conference that the "share of supply test" under the Enterprise Act 2002[1] constitutes a "flexible test which, in practice, has meant that the CMA has consistently been

[1] Pursuant to the "share of supply" test under the Enterprise Act 2002, the CMA has jurisdiction to review a merger if the parties have a share of supply in the UK (or in a substantial part of the UK) of 25% or more in relation to goods or services of any description.

able to exert jurisdiction over transactions [even where] the turnover of the target was limited, but the value of the deal was high."[2] In particular, Illumina/PacBio shows that the CMA is willing to assert jurisdiction even in a case where (i) the target has little to no turnover in the UK and (ii) there is a negligible increment in the combined market shares of the combined entity following the transaction – provided that the acquiring company has a significant market presence in the UK. In other words, the CMA is able to stretch its jurisdiction to a case where a transaction (arguably) has little to no impact or change to the distribution of market shares, market power or market dynamics generally in the UK. Illumina/PacBio is not the first decision of its kind in this regard: in its recent decision to initiate an in-depth investigation of the proposed acquisition by Sabre Corporation of Farelogix Inc., stressing the "public importance" attributed to its role in effectively regulating merger activity, the CMA found the share of supply test to be satisfied merely by virtue of the parties' proportion of sales to a *single* customer in the UK, and on the "two-sided features" of supply of certain services, notwithstanding the fact that the target had no customers in the UK. This illustrates the CMA's almost limitless scope to define categories of goods and services and choose metrics in order to satisfy the jurisdictional share of supply test by proving an overlap and combined share of supply exceeding the 25% threshold.

Second, in light of the global scope of the relevant markets, the CMA's review in Illumina/PacBio was focused on the worldwide DNA sequencing markets. It is evident from the CMA's reasoning that the discussion of whether the transaction would reduce competition is primarily premised on the impact of the merger at a global level, and not on any UK-specific market.

Close cooperation between the CMA and the US antitrust authorities

Finally, Illumina/PacBio and Roche/Spark both highlight the close cooperation and communication the FTC (and the Department of Justice) and the CMA engage in when the two agencies are simultaneously reviewing a transaction, as is often the case in biopharmaceutical mergers. Illumina/PacBio also illustrates the pitfalls of undergoing simultaneous investigations across jurisdictions. When a deal is subject to multiple investigations, enforcers are liable to gain leverage and time that they would not otherwise enjoy. This played out to the detriment of the Illumina/PacBio transaction where the FTC not only gained additional time for its investigation, but also gained procedural benefits. Because the deal was stalled in the CMA process, the FTC was able to avoid a federal court action and could opt, instead, to litigate exclusively through the administrative process.

This trend of cross-Atlantic cooperation can be expected to continue going forward. Parties should recognize the timing consequences by negotiating prudent end dates in merger agreements, and carefully managing the several regulators' iterative competition reviews in guiding transactions to successful completion.

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[2] The share of supply test can also be applied to share of demand, although the CMA does this infrequently.

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