ANTICIPATED ACQUISITION BY ILLUMINA, INC. OF PACIFIC BIOSCIENCES OF CALIFORNIA, INC.

Issues Statement

1 August 2019

The reference

1. On 27 June 2019, the Competition and Markets Authority ('CMA'), in exercise of its duty under section 33(1) of the Enterprise Act 2002 ('the Act'), referred the anticipated acquisition by Illumina, Inc. ('Illumina') of Pacific Biosciences of California, Inc ('PacBio') ('the Proposed Merger') for further investigation and report by a group of CMA panel members ('the Group').

2. In exercise of our duty under section 36(1) of the Act, we must decide:

   (a) whether arrangements are in progress or in contemplation which, if carried into effect, will result in a relevant merger situation; and

   (b) if so, whether the creation of that situation may be expected to result in a substantial lessening of competition (SLC) within any market or markets in the United Kingdom for goods or services.

3. In this statement, we set out the main issues that we are likely to consider in reaching our decision. This does not preclude the consideration of any other issues which may be identified during the inquiry. Parties wishing to comment on this Issues statement are encouraged to read the CMA's decision in phase 1 (the Phase 1 Decision)[1] which sets out basis on which the CMA concluded that the Proposed Merger gave rise to a realistic prospect of an SLC.

4. Throughout this document we refer to Illumina and PacBio collectively as 'the Parties' or, for statements referring to the future, the 'Merged Entity'.

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[1] https://assets.publishing.service.gov.uk/media/5d307b9ded915d2fe8096fb8/Illumina_PacBio_Full_textP1_Redacted.pdf

Background

5. On 1 November 2018, Illumina agreed to acquire 100% of the share capital of PacBio.

6. This this an anticipated merger and completion is conditional upon clearance by the CMA.[2] The Parties informed us that the Proposed Merger is also the subject of review by the Federal Trade Commission in the USA.

The Parties

7. Illumina is a global genomics company that is publicly listed on the NASDAQ stock exchange. Illumina develops, manufactures and commercialises systems, consumables, bioinformatics and services used for genetic analysis worldwide. Illumina's systems include second generation, short read DNA sequencing instruments based on its Sequencing by Synthesis (SBS) technology as well as DNA microarray scanners.

8. Illumina also provides product support services for its systems as well as genetic analysis services powered by its sequencing and microarray technologies. Illumina's sequencing systems use consumables that include library preparation kits, reagents, sequencing kits and flow cells. The sequencing data that they produce is interpreted with specific bioinformatics software and applications.

9. Illumina's customers include a variety of government and not-for-profit genomic research institutes, academic institutions, hospitals, genomics centres as well as pharmaceutical, biotechnology, agrigenomics, clinical and diagnostic laboratories, and consumer genomics companies. Illumina's turnover in 2017 was £2.1 billion, of which £[✂] was attributable to the UK.

10. PacBio is also a global genetics company that is publicly listed on the NASDAQ stock exchange. PacBio develops, manufactures and commercialises third generation, native long read[3] DNA sequencing systems based on its Single Molecule, Real Time (SMRT) technology. PacBio's long read systems run on proprietary consumables that include library preparation kits, sequencing kits and SMRT Cells commercialised by PacBio. The sequencing data produced is interpreted with bioinformatics tools provided by

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[2] Paragraph 8 of the Parties' Merger Notice.
[3] The term native long read sequencing is used to differentiate PacBio's technology (which generates single, contiguous long reads) from 'linked long read' or 'associated short read' solutions, such as that offered by 10x Genomics, which use barcoding techniques applied as part of the library preparation workflow to order and assemble short reads together to create an artificial long read. For the purposes of this Issues Statement, the term 'long read' shall be used to mean native long read, unless indicated otherwise.

PacBio and by third parties. PacBio's customers include government and not-for-profit genomic research institutes, genomics centres, pharmaceutical companies and agricultural companies. PacBio also provides product support services for its native long read sequencing systems.

11. PacBio introduced its new Sequel system (Sequel II) on 24 April 2019 following a (reportedly-successful) early access program.[4] Sequel II is based on the same underlying SMRT technology as previous PacBio sequencing systems but now includes the SMRT Cell 8M chip which increases the number of potential observations (the number of DNA molecules analysed) from 1 million to 8 million, increasing output and reducing cost of sequencing considerably as a result. PacBio's turnover in 2017 was £72.4 million, of which £[✂] was attributable to the UK.

Our intended inquiry

12. Below we set out some specific areas of our intended assessment in order to help parties who wish to make representations to us. However, these will not be the only areas for our assessment. For example, we will also look at key characteristics of how the market operates, the relevant counterfactual,[5] and any evidence available to us in relation to efficiencies arising from the Proposed Merger.[6]

The Parties' services and markets in which they operate

13. Market definition provides a framework for assessing the competitive effects of a merger for a relevant product and geographic market. It involves an element of judgement. The relevant market contains the most significant competitive alternatives available to the customers of the merging firms and the most relevant constraints on the behaviour of the merging firms.[7]

14. However, the boundaries of a market do not determine the outcome of the analysis of the competitive effects of the merger, as it is recognised that there can be constraints on merging parties from outside the relevant market, segmentation within the relevant market, or other ways in which some

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[4] PacBio ran a beta program in which a small number of customers were given early access to the new 8M technology. The early access program was intended to optimise the performance of the SMRT®Cell 8M chip and other components of the Sequel II System (including chemistry and software), to develop reference materials, and pre-emptively address any technological issues that may arise prior to making the product fully available commercially.
[5] Merger Assessment Guidelines, Section 4.3.
[6] Merger Assessment Guidelines, Section 5.7.
[7] Merger Assessment Guidelines, Section 5.2.1.

constraints are more important than others. We will take these factors into account in our competitive assessment.[8]

15. In general, we note that market definition and the analysis of competitive effects largely overlap since both are driven by considerations relating to the 'closeness' of substitution between the Parties' offerings and those of alternatives.

Product Market

16. The Parties overlap horizontally in the supply of DNA sequencing systems and associated peripherals. On the basis of the information obtained to date (including during the Phase 1 investigation), we think the supply of DNA sequencing systems on a worldwide basis is the appropriate frame of reference to consider the Proposed Merger.

17. We will consider whether there are narrower or broader segmentations where the Parties' offerings may compete in our examination of the closeness of competition. See the section on 'Assessment of the competitive effects of the Proposed Merger' below. We welcome comments on this.

Geographic market

18. The statutory test for this inquiry is whether the Proposed Merger may be expected to result in an SLC within any market(s) in the UK for goods or services. We will, therefore, focus on competitive effects in the UK and on the effects on UK customers.

19. In doing so, we will take account of global matters to the extent that they have competitive effects in the UK, both currently and in the future. We will collect both UK and global data from the Parties on matters such as sales, prices and margins, most likely with more detailed data for the UK sales and aggregated data for global sales. We will consider all relevant global competitors and will analyse any economic incentives of the Parties in the context of their operations in a global market.

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[8] Merger Assessment Guidelines, Section 5.2.2.

Assessment of the competitive effects of the Proposed Merger

Counterfactual

20. We will consider the possible effects of the Proposed Merger on competition compared with the degree of competition in the counterfactual situation (that is, the situation that would have been most likely to have arisen in the short to medium term absent the Proposed Merger).

21. For anticipated mergers, such as this, we generally adopt the prevailing conditions of competition as the counterfactual against which to assess the impact of the merger. We may examine several possible scenarios, one of which may be the continuation of the pre-merger situation but ultimately only the most likely scenario will be selected as the counterfactual.

22. We will typically incorporate into the counterfactual only those aspects of scenarios that appear likely on the basis of available facts and our ability to foresee future developments. We seek to avoid any spurious claims to accurate prediction or foresight.

23. Since announcing the Proposed Merger, PacBio has launched its 'Sequel II' sequencing system. PacBio introduced its Sequel II instrument on 24 April 2019 following a reportedly-successful early access program. Sequel II is based on the same underlying SMRT technology as previous PacBio sequencing systems but now includes the SMRT Cell 8M chip which increases the number of potential observations (the number of DNA molecules analysed) from 1 million to 8 million, increasing output and reducing cost of sequencing considerably as a result. We will therefore consider a counterfactual in which PacBio were to operate the Sequel II system (alongside its other commercialised instruments, eg Sequel I) independently of Illumina. In addition to the counterfactual, we intend to consider the impact of the launch and commercialisation of the Sequel II system in our competitive assessment.

Theory of Harm

24. The term 'theory of harm' describes the possible ways in which an SLC could arise as a result of a merger. The theory of harm often provides the framework for our analysis of the competitive effects of a merger. Identifying a theory of harm in this issues statement does not preclude an SLC from being identified on another basis following further work by the CMA or the receipt of additional evidence. We welcome views on the theory of harm described below.

25. We will assess whether the Proposed Merger gives rise to an SLC in the supply of DNA sequencing systems on a worldwide basis. This is a horizontal, unilateral effects theory of harm.

26. A unilateral effects theory of harm is that the removal of one party which provides a competitive constraint or is expected to provide a competitive constraint, allows the merged entity to increase prices, lower quality, reduce the range of their services and/or reduce product development and the pace at which innovation is conducted and rolled out, all relative to the counterfactual.[9] In general, where products or services are differentiated, for example by branding or quality differences, unilateral effects are more likely where the merger firms' products compete closely.[10]

27. In this case, the Parties overlap in the supply of DNA sequencing systems on a worldwide basis. We will assess whether, as a result of the loss of direct competition between the Parties, whether now or in the future, the Merged Entity would have limited incentive to compete on price (whether instrument price, system price or some other cost metric), could deteriorate quality and/or, as is particularly relevant in this case, reduce or re-focus innovation, including the pace of innovation, or delay or reduce the development and/or supply of new products to the market.

28. In general, for this theory of harm (as set out in paragraph 25) to be substantiated, the following conditions must be met:

    (a) The Parties are, or are expected to become, close competitors in the supply of DNA sequencing systems.

    (b) Rivals are unlikely to replace effectively the competitive constraint that the Parties exert on one another, or that one Party exerts on the other if they constrain each other asymmetrically, in the supply of DNA sequencing systems.

    (c) Rivals are unlikely to enter or expand in the market for the supply of DNA sequencing systems within a reasonable timeframe and thereby replace the competitive constraint that would be lost through the Proposed Merger. Further consideration of this is set out in the section on countervailing factors below.

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[9] Merger Assessment Guidelines, Section 5.4.1.
[10] Merger Assessment Guidelines, Section 5.4.6

Limited price decrease and reduced quality as a result of the Proposed Merger

29. When assessing the Merged Entity's limited incentives to compete on price (whether instrument price, system price, or some other cost metric), and ability to reduce the quality or the range of services offered as a result of the Proposed Merger, we intend to estimate market shares by revenue using data from the Parties and third parties and consider how these are likely to evolve in future. We will also consider evidence from the Parties' internal documents, valuation models, profit forecasts under future scenarios, views of equity and market analysts, third party questionnaire responses and views expressed during calls, and third party internal documents.

Reduction or refocusing of innovation as a result of the Proposed Merger

30. When assessing the Merged Entity's ability and incentive to reduce or refocus innovation, including the pace of innovation, and product market release, as a result of the Proposed Merger, in addition to the evidence listed at paragraph 29 above, we intend to consider evidence of the Parties' and third parties' patent portfolios and current and future spend on research and development.

31. Due to the dynamic and rapidly-evolving nature of DNA sequencing technologies, when assessing the impact of the Proposed Merger on prices, the quality of the Parties' products, and innovation, we intend to undertake a forward-looking assessment of the Proposed Merger and its likely impact on the market. This will mean that, where appropriate, we will place weight on evidence that attempts to assess the future position, in addition to evidence which gives a historical view of the industry and competitive constraints within it.

32. We will also consider whether any competitive effects of the Proposed Merger vary significantly according to type of customer or product.

33. We welcome views on the theory of harm set out above.

Countervailing factors

34. We will consider whether there are countervailing factors which are likely to prevent or mitigate any SLC that it may find.

Entry and expansion

35. The CMA will consider evidence on entry and/or expansion by third parties and whether such entry or expansion would be timely, likely or sufficient to

prevent any SLC from arising as a result of the Proposed Merger.[11] To do this, the CMA will examine the plans of third parties including their internal documents, consider the costs and time necessary for competitors to develop and launch competing products and services and the expected effects, and examine other factors that might inhibit entry or the expansion of competitors such as any scale or incumbency advantages. We will also consider whether the Proposed Merger may increase barriers to entry and/or expansion by, for example, increasing the Merged Entity's ability and incentive to defend its position in the market by foreclosing the entry and expansion of competing suppliers of sequencing systems by the following strategies:[12]

(a) Using the enforcement, or the threat or perceived threat of enforcement, of the Merged Entity's intellectual property rights.

(b) Offering bundling or targeted discounting to customers who purchase both short read and long read types of sequencing systems.

Efficiencies

36. We will examine any evidence put to us in relation to efficiencies arising from the Proposed Merger. In particular, we will consider whether there are merger-specific rivalry-enhancing efficiencies such that the Proposed Merger may not be expected to result in an SLC.

Possible remedies and relevant customer benefits

37. Should we conclude that the Proposed Merger is expected to result in an SLC in one or more markets, we will consider whether, and if so what, remedies might be appropriate, and will issue a further statement.

38. In any consideration of possible remedies, we may in particular have regard to their effect on any relevant customer benefits that might be expected to arise as a result of the Proposed Merger and, if so, what these benefits are likely to be and which customers would benefit.

Responses to the issues statement

39. Any party wishing to respond to this issues statement should do so in writing, by no later than **5pm on Thursday 15 August 2019**. Please email Illumina_PacBio@cma.gov.uk or write to:

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[11] Merger Assessment Guidelines, Section 5.8.
[12] Merger Assessment Guidelines, Section 5.8.13.

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