Anticipated acquisition by Illumina, Inc (Illumina) of Pacific Biosciences of California, Inc. (PacBio)

Summary of Provisional findings

Introduction

1. The Competition and Markets Authority (CMA) has provisionally found that the anticipated acquisition by Illumina, Inc. (Illumina) of Pacific Biosciences of California, Inc. (PacBio) (the Proposed Merger) may be expected to result in a substantial lessening of competition (SLC) due to horizontal competition concerns in the market for the supply of next generation sequencing (NGS) systems in the UK. For the purpose of these findings, NGS systems includes both second generation short read systems and third generation long read systems.

2. This report and the appendices constitute the CMA's provisional findings. The CMA now invites any interested parties to make representations on these provisional findings by **14 November 2019**. Parties should refer to **the notice of provisional findings** for details of how to do this.

3. Alongside these provisional findings, we have published a notice of possible remedies, which sets out the CMA's initial views on the measures that might be required to remedy the SLC that we have provisionally found. We also invite submissions from interested parties on these initial views by **7 November 2019.**

Background

4. The CMA is required to answer the following questions:

   (a) Whether arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation for the purposes of the Enterprise Act 2002 (the Act).

   (b) If so, whether the creation of that situation may be expected to result in a SLC within any market or markets in the UK for goods or services.

5. If one or more SLCs are found, the CMA must decide what action it might take for the purposes of remedying them.

The Parties

6. Illumina is a global genomics company that is incorporated in Delaware (US), headquartered in California (US), and 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. Its global turnover in 2018 was $3.3 billion derived from an installed base of around 13,000 instruments.

7. PacBio is a global genetics company that is incorporated in Delaware (US), headquartered in California (US), and is publicly listed on the NASDAQ stock exchange. PacBio develops, manufactures and commercialises third generation, native long read DNA sequencing systems based on its Single Molecule, Real Time (SMRT) technology. PacBio's worldwide turnover in 2018 was $78.6 million. PacBio introduced its new Sequel system (Sequel II) on 24 April 2019 following a (reportedly-successful) early access program.

8. We refer to Illumina and PacBio collectively as the Parties and for statements referring to the future post-merger, as the Merged Entity.

The industry

9. DNA contains the hereditary material for any living organism, encoded as a series of particular molecules called nucleotides (or 'bases'). DNA is composed of four different types of nucleotide that are linked together into strands in the form of a double-helix that can reach lengths into the millions. DNA sequencing is the process of determining the order of these nucleotides in a particular sample of DNA.

10. There are a number of specific technological approaches to conducting this sequencing being offered and/or developed by different organisations, many of which rely on patent-protected or proprietary techniques. However, most approaches fundamentally involve incorporating labelled versions of the nucleotides into a strand of DNA sequentially and identifying each base in order as it is incorporated.

11. The first DNA sequencers were developed in the 1970s by biochemist Frederick Sanger. The technique he developed is known as the Sanger sequencing method and represents what are now called 'first generation'

sequencers. In 2005 a new generation of sequencers emerged, referred to as second generation, or short read sequencers. Since 2010, a small number of companies have developed ‘single molecule’ sequencers, sometimes referred to as third generation sequencing or ‘native long read’ sequencing. In these provisional findings we refer to both second generation (short read) and third generation (long read) sequencing systems, and together as next generation sequencing (NGS) systems.

12. Other suppliers of DNA sequencing systems include:

(a) **Beijing Genomics Institute (BGI)** is a genomics company founded in 1999 to represent China in the Human Genome Project and launched its first short-read sequencing system in 2015.

(b) **Oxford Nanopore Technologies (ONT)** is a privately held, UK based, company that was spun out of the University of Oxford in 2005 to develop and commercialise native long-read DNA sequencing systems.

(c) **Thermo Fisher Scientific (Thermo Fisher)** supplies short-read DNA sequencing instruments under the SOLiD system and Ion Torrent system, as well as being the leading supplier of first-generation Sanger sequencing systems.

(d) **QIAGEN** provides short-read sequencing systems, as well as universal solutions which can be used with any second generation sequencer including Illumina’s. These solutions include library preparation, assays, and bioinformatics software. On 7 October 2019 QIAGEN announced that it was suspending any ongoing NGS instrument development activities and that it had entered into a new strategic collaboration with Illumina to deliver sequencing-based in-vitro diagnostic (IVD) tests.

The Proposed Merger

13. On 1 November 2018, the Parties signed a merger agreement (the ‘Merger Agreement’) to acquire PacBio for a total price of approximately $1.2 billion (£930 million).

14. The Proposed Merger is conditional upon approval by PacBio's shareholders, which was given on January 24, 2019, as well as clearance by the US and UK competition authorities.

Our provisional findings

Relevant merger situation

15. We have provisionally found that arrangements are in progress or in contemplation which, if carried into effect, will result in the creation of a relevant merger situation within the meaning of the Act.

16. The Parties both supply NGS systems in the UK. As a result of the Proposed Merger the Parties would cease to be distinct and their combined share of supply would exceed 25%. We have therefore established that there is a sufficient nexus within the UK on a share of supply basis to give us jurisdiction to investigate the Proposed Merger.

Counterfactual

17. Before we assess the effects of the Proposed Merger, we determine what we would expect the competitive situation to be absent the Proposed Merger – the 'counterfactual'. The counterfactual is a benchmark against which the expected effects of a merger are assessed.

18. Our provisional conclusion is that the most likely situation absent the Proposed Merger, and therefore the appropriate counterfactual, is one in which PacBio would remain an independent entity and the prevailing conditions of competition would continue. These prevailing conditions would include levels of investment and innovation by both Illumina and PacBio commensurate with their pre-merger business plans.

Market definition

19. Market definition provides a framework for the analysis of the competitive effects of a merger. Market definition is a useful analytical tool but is not an end in itself and identifying the relevant market involves an element of judgment. The boundaries of the market do not determine the outcome of the CMA's analysis of the competitive effects of a merger in a mechanistic way.

20. The Parties submitted that short read sequencing (as supplied by Illumina) and long read sequencing (as supplied by PacBio) are complementary technologies and fall into distinct product markets.

21. In making a judgement on market definition in this case, we have taken into account the dynamic nature of this industry and the forward-looking nature of our assessment. Much of the evidence we rely on in determining the relevant market is also relevant to the competitive assessment as we analyse the

closeness of competition between Illumina, a short read sequencing system provider and PacBio, a long read sequencing system provider.

22. Having considered the Parties' submissions and a number of other sources of evidence, such as internal documents from the Parties and evidence from customers and competitors, our provisional view is that the relevant product market in which to assess the effect of the Proposed Merger is the NGS systems market.

23. The Parties submitted that the relevant geographic market is worldwide. This is consistent with our analysis of the evidence provided to us. We did examine whether China should be excluded from the geographic market, on the basis of different competitor strengths. However, we do not consider that the inclusion or exclusion of China would make a material difference in our assessment.

24. Accordingly, our provisional view is that the relevant geographic market for these products is worldwide.

Competitive assessment

Theory of Harm

25. Theories of harm describe the possible ways in which an SLC could arise as a result of a merger and provide the framework for our analysis of the competitive effects of a merger. In this case, we have investigated one horizontal unilateral theory of harm: the loss of competition as a result of the Proposed Merger in the supply of NGS systems in the UK.

26. As a result, we have investigated whether the Proposed Merger is likely to lead to the following:

    (a) The reduction of current and future competition in areas where Illumina and PacBio overlap or are likely to overlap in the future. This competition may take the form of competition in the purchasing decisions of customers over the acquisition of a sequencing system ("competition for sequencing dollars"); competition in the trade off made by customers between the use of short read and long read technologies in certain projects; and/or

    (b) A deterioration in the future competitiveness of the long-read sub-segment, through, for example, its impact on Illumina's incentives and actual intentions to develop technologies that compete directly with

PacBio's long read systems leading to the elimination of Illumina as a potential future, independent competitor in the long read sub-segment.

Nature of competition

27. The Parties' submissions suggest we should only be concerned about competition occurring at the 'use case' level and, while the industry is dynamic, it is not characterised by competition for the market, and nor should the CMA be concerned about the migration of customers from one system to another over time.

28. The Parties submitted that the terms 'application' and 'use case', while at times used interchangeably in the sequencing industry, have very different meanings. Application is a broader concept than use case and refers to a collection of use cases. Each use case, in turn, has its own distinct characteristics and requirements which reflect the specific aim of the investigation, the type of starting material, the number of samples involved, any industry-specific regulatory requirements, etc.

29. The Parties submitted that any competition that takes place, takes place at the 'use case' level only. The Parties argued that their respective instruments are use case specific and that there is therefore no competition between their technologies.

30. Competition is a process of rivalry that takes place over time. The evidence we have seen, from the Parties' internal documents and competitors, indicates that this is a dynamic market, which is growing and evolving quickly. We therefore provisionally conclude that it is important to assess the Proposed Merger in a dynamic context.

31. The evidence we have seen, including the way that customers think about choosing which NGS systems to use for their projects, also indicates that thinking about competition narrowly, for example, only at the 'use case' level, is not the appropriate way to assess this Proposed Merger. We also provisionally conclude that firms are able to tailor their offerings according to customers and when doing so they take into account that customers think about options at application and project level and also across their differing projects, not just at the 'use case' level. The same is true both for the Parties and other competitors in the NGS systems market.

32. We also consider that there are a number of different factors which customers consider important, with read accuracy, length and throughput / cost appearing to be most important, although their relative importance will depend on the customer, research question or project(s). NGS systems are

differentiated products and customers will choose between such systems on the basis of the factors which are most important to them, their project, or across a number of projects.

33. We have also found that the Parties are able to set prices individually for customers based on the sequencing they wish to conduct and the options that are likely to be available to them. This ability to price discriminate means the Parties have the ability (and would continue to have the ability post-merger) to worsen prices selectively for those customers whose options are more limited without increasing prices for others and can consequently avoid the risk that those other customers switch away as a result of the price increase.

34. We therefore consider it important to assess how the Parties view each other now and in the future, how they have reacted to each other in the past, how customers perceive their options, the development of the technologies and the constraint posed by competitors now and in the future.

Our assessment of the competitive effects of the Proposed Merger

35. Our investigation has collated and assessed a large volume of evidence on the impact of the Proposed Merger. To reach our conclusions we have used our judgement to evaluate the weight we should place on different pieces of this evidence, in particular:

    (a) We place the most weight on the Parties' internal documents which are particularly informative in this dynamic market because they provide context on how the market is developing and how competition takes (and will take) place, while many other forms of evidence provide a more static perspective. In addition, the Parties' internal documents provide us with their actual plans. We note that we have been able to gather a large number of these documents, we have a good understanding of the context in which they were produced, many shed light directly on issues central to our investigation and we are able to discern a clear and consistent picture from them.

    (b) We place substantial weight on customer evidence. This is particularly in relation to technical questions that customers (as scientific researchers) are well placed to answer, such as on how they currently make purchasing decisions. However, we place limited weight on customers' overall views of the Proposed Merger as these reflect customers' perspectives on the immediate impact of the merger – principally the improvements they consider will result in the short term from Illumina's ability to commercialise and fund the development of PacBio's technology. They take no, or limited account, of the broader impact of the

merger on competition, R&D and future entry, in a highly dynamic market over the short, medium and long term.

(c) We place substantial weight on competitor evidence in relation to their internal documents and expansion plans. In particular, we consider that competitors' internal documents provide evidence on the extent to which they consider the Parties as competitors and the constraint they perceive between different technologies, while their expansion plans provide evidence of how this might change in the future.

(d) With the exception of market shares, which we believe provide useful context in showing the current structure of the market in which the Proposed Merger is taking place, we place only limited weight on the quantitative evidence available, such as the econometric analysis and sales forecasts. In general, such evidence is less informative in the context of a merger in this dynamic market. In this case, even when some forecasts are available, we think their use is limited, given the methodology and very specific purpose they were created for.

36. The market for NGS systems is highly concentrated both worldwide and in the UK due to Illumina's very strong market presence. Illumina possesses a substantial degree of market power with approximately 80% of the worldwide NGS systems market and 90% share in the UK. Given the strength of Illumina's market position, the removal of a competitor, even one with currently limited market share like PacBio, would have a significant impact on competition. We have therefore looked carefully at whether there are situations where the Parties are (or would become in the foreseeable future) substitutes, which is where any loss of competition would most clearly arise.

37. The evidence shows that there are many uses for each of the Parties' instruments and the extent of competition between them will vary due to the differences in the technologies employed. In a significant portion of the current market, the Parties are likely to be seen as complements rather than competitors and direct competition between them would be less likely. However, there is significant evidence of direct competition between the Parties in some situations at present. There is also clear evidence that this market is dynamic and that the competitive overlap and closeness of competition between the Parties is likely to increase in the future as R&D is devoted to improving each Party's technology to address a wider range of use cases, applications and/or projects.

38. We have seen from the Parties' internal documents that the Parties regularly track each other and adapt their strategies to reflect each other's developments. This shows that they consider each other as an important

competitive threat both on a day-to-day level and a strategic level. This evidence is consistent across both Parties' documents, and across a wide range of internal documents produced by a number of senior authors over a period of time. These documents encompass strategy discussions, technology reviews, the preparation of support materials for sales executives, and commentary on specific competitive situations. PacBio's internal documents regularly monitor Illumina and include emails where PacBio identifies instances when it believes it can win business from Illumina and has been trying to do so for some time. Illumina's documents discuss PacBio as a competitive threat and indicate that Illumina has taken action or has considered taking action in response to this competitive threat from PacBio.

39. This was supported by customers who noted that short read and long read are currently substitutable for at least some projects and noted areas where long read sequencing had already displaced short read sequencing in their work.

40. Moreover, the evidence shows that this market will continue to evolve in the future. We have seen a number of internal documents from both Parties which show that the Parties will compete more closely in the future because of improvements to PacBio's technology. According to Illumina's internal documents, PacBio is likely to substantially impact Illumina's business in the future.

41. This view was also supported by customers and competitors, who said that long read technologies will be more prevalent in the future and suggested that this is likely to be at the expense of short read technologies.

42. We have therefore provisionally found that currently the Parties are competing for the supply of NGS systems in relation to certain purchasing decisions, uses, applications and/or projects. We have also seen consistent evidence that demonstrates that long read technologies are improving and that Illumina as well as PacBio and ONT see long read sequencing as a critical and growing part of NGS systems in the future. Evidence from Illumina's internal documents and its submissions show that Illumina also considers long read sequencing as a critical and growing part of NGS systems in the future and absent the Proposed Merger would be well placed to develop and launch such a system.

43. Recent developments of the PacBio system (including the launch of Sequel II) have resulted in customers being increasingly able and willing to move a portion of their workflow and budgets from Illumina's to PacBio's technology, and the evidence suggests that this places competitive pressure on Illumina. Currently the Parties compete for sales in relation to some types of projects

and to overall purchasing decisions. It is likely that this competition will intensify in the future and that there is evidence from the Parties' internal documents that the Parties also consider this to be true.

44. We have provisionally found that innovation is a key aspect of competition in this market and that the Parties perceive each other as important strategic rivals. Their common desire to be the preferred sequencer for as many projects and as large a share of aggregate spend as possible is substantially driving their current innovation efforts and has been a key factor driving their innovation efforts over a number of years. This evidence shows that currently PacBio's improvements to its technology incentivise Illumina to improve, and as the Parties' sequencing systems increasingly overlap in the future, absent the Proposed Merger, this race for innovation is expected to intensify. In our provisional view the Proposed Merger will eliminate the threat of PacBio on Illumina (and vice versa) which is a factor that currently drives R&D and innovation.

45. Our provisional view is that the Proposed Merger is likely to result in a shift in the direction of the Parties' R&D away from research they would have done, and products they would have launched. For example, given the importance Illumina attaches to having a presence in long read sequencing, we think it likely that absent the Proposed Merger Illumina would be researching long read technologies with a view in future to launch its own long read system. The Proposed Merger therefore reduces the potential future number of options for customers and projects that require a long read technology. Similarly, absent the Proposed Merger, PacBio would be likely to invest in research where it would compete with Illumina's instruments, but should the Proposed Merger proceed it will instead be incentivised to focus its R&D towards uses where its systems will be complementary to those of Illumina.

46. The Parties' internal documents show that Illumina considers BGI, PacBio and ONT to be its main competitive threats. Of these three, Illumina is most focused on BGI on a worldwide basis, although BGI is not currently fully active in the UK. Illumina also monitors ONT, though some documents note limitations to the accuracy of its technology. PacBio's focus is primarily on ONT and Illumina as the main competitive threats, with ONT being the closest of these two.

47. While the Parties face competition from other providers of NGS systems (ONT, BGI, Thermo Fisher and QIAGEN), these rivals are not likely to sufficiently constrain the Merged Entity. Based on the evidence examined, we provisionally consider that the level of competitive constraint exercised by the Parties' competitors is currently limited or focused on particular niches and is

not expected to increase significantly in the foreseeable future. More specifically:

(a) ONT is currently monitored as a strong competitor by both of the Parties. We provisionally consider that ONT would increasingly represent a strong competitive threat to both Illumina and PacBio. We recognise that ONT places some constraint on the Merged Entity and will continue to do so going forward. However, we do not believe that the presence of ONT will be sufficient to replace the loss of the competitive constraint currently provided by PacBio, given the size of the Merged Entity, the lack of remaining competitors and that the Parties remain sufficiently close competitors to one another such as to raise concerns that the loss of competition between them as a result of the Proposed Merger would be significant.

(b) BGI's products are positioned as a direct alternative to Illumina's short read technology. However, BGI is not currently actively selling its instruments in the UK. As such, we provisionally consider that while BGI would likely increase its level of market penetration and impose a stronger constraint on the Parties worldwide, it may not gain any substantial market traction within the UK in the foreseeable future.

(c) Thermo Fisher's focus is on clinical applications of the NGS systems and it has not been able to gain any wider market traction so far. Based on this, the CMA provisionally considers that the level of competitive constraint imposed by Thermo Fisher is limited and would be unlikely to increase to any significant extent in the foreseeable future.

(d) Similarly, QIAGEN is a small competitor who is mainly active in the clinical segment and has very limited market shares in the supply of NGS systems. Furthermore, it is unclear whether QIAGEN will remain an independent competitor, following its announcement on 7 October 2019 that it will enter into a collaboration with Illumina. Based on this, the CMA provisionally considers that QIAGEN currently imposes a limited competitive constraint which is unlikely to increase in the foreseeable future and may in fact largely disappear going forward depending on nature and extent of the collaboration with Illumina.

48. Evidence on closeness of competition between the Parties (current and future), as well as the Parties' high combined market share demonstrates that there would be a substantial loss of competition brought about by the Proposed Merger. Further, evidence on current and likely future strength of the remaining competitors in the market demonstrates that the Proposed Merger would result in the combination of two of only a small number of

options in this highly concentrated market. In our provisional view, the Proposed Merger may be expected to result in a substantial lessening of competition in the market for the provision of NGS systems in the UK, absent any countervailing factors which are discussed below.

Countervailing factors

49. In considering whether a merger may be expected to result in an SLC, the CMA will consider factors that may mitigate the initial effect of a merger on competition ('countervailing factors'), which in some cases may mean that there is no SLC. These factors include the responses of others in the market to the merger, for instance the entry by new providers or expansion by existing providers; the ability of customers to exercise buyer power; and the effect of any rivalry-enhancing efficiencies arising as a result of the merger.

50. We have provisionally found that the NGS systems market has high barriers to entry and expansion. This is due to the need to develop a novel technology which does not infringe existing patents (and is sufficiently superior or differentiated that it could challenge a strong incumbent), as well as the cost and time associated with developing the technology, obtaining patent protection, and the need to commercialise it by reaching sufficient scale.

51. In addition, we have found there are also significant barriers to customers switching NGS systems. Historically, there have been numerous instances of potential entrants which were not able to successfully develop and commercialise NGS technologies. Although the high projected growth of the market has resulted in numerous attempts to develop new NGS systems, many of the potential entrants are so early in their development that it is not possible for us to speculate on how they might evolve in the future with any degree of accuracy. The majority of potential entrants have products whose entry to the market does not, at present, seem imminent or likely; and in a small number of cases where the research is more advanced, entry still does not appear to be timely and may be restricted to small or niche parts of the market which would likely be insufficient to deter or defeat attempts by the Parties to exploit the substantial lessening of competition resulting from the Proposed Merger.

52. Our provisional conclusions are that there are high barriers to entry and expansion in the NGS systems market, and the evidence does not support the view that timely, likely and sufficient entry or expansion will outweigh the SLC we have provisionally identified.

53. In relation to countervailing buyer power, we examined Illumina's very high existing market share and the competitive conditions in the NGS systems

market, along with views from customers and competitors. Although certain customers may be a better placed than others to negotiate with the Parties (for example due to their size and/or relative importance in driving future research), it is unlikely that even large customers would be able to exert sufficient countervailing buyer power on the Merged Entity. Furthermore, even if certain customers were able to exercise a degree of countervailing buyer power, due to the prevalence of bilateral negotiations in the NGS systems market, any other customers would remain exposed to the effects of any substantial lessening of competition arising from the Proposed Merger.

54. On this basis, we have provisionally concluded that there is insufficient countervailing buyer power to outweigh the SLC we have provisionally identified.

55. Finally, in relation to efficiencies, the Parties have submitted a number of areas which they consider would result in rivalry-enhancing efficiencies following the Proposed Merger, particularly the potential for improving commercial operations, and accelerating innovation. We consider that the Merged Entity would likely have the ability to improve on PacBio's commercial operations, and to speed up the development of PacBio's technology through higher levels of investment and existing know-how. However, the evidence available provides little support that the Merged Entity would have the incentive to implement all of these changes as described (eg whether increasing aggregate research and development in the manner submitted would be the most profitable strategy). We also consider that there is insufficient evidence on the extent to which any of these changes would be expected to result in an increase in rivalry (and benefits to customers), or the extent to which any potential efficiencies are merger-specific, compared to the counterfactual.

56. Accordingly, our provisional conclusion is that there is no compelling evidence that the Proposed Merger would result in rivalry-enhancing efficiencies that would be timely, likely, and sufficient to outweigh the SLC we have provisionally identified.

Provisional conclusions

57. As a result of our inquiry and our assessment, we have provisionally concluded that the anticipated acquisition by Illumina of PacBio would result in the creation of a relevant merger situation.

58. We have provisionally concluded that the Proposed Merger may be expected to result in an SLC in the market for the supply of NGS systems in the UK.

59. We provisionally conclude that the adverse effect arising from the identified SLC would be that the Merged Entity would have less incentive to compete and that this would result in reduced choice, an increase in prices, deterioration in quality, deterioration in service and/or loss of innovation or re-focus their own innovation.