Response to Notice of Possible Remedies

- 1. This response to the CMA's Notice of Possible Remedies ("NPR") proposes remedies that address the CMA's provisional substantial lessening of competition ("SLC") findings, and identifies the important relevant customer benefits ("RCBs") that would result from the proposed remedies. More specifically, the RCBs of the Transaction include the following:¹
 - (i) Wider distribution of/access to PacBio's products and technology by enabling PacBio to benefit from Illumina's global production, and support and service infrastructure;
 - Increased adoption of PacBio's systems by clinical and diagnostic customers by enhancing PacBio system quality with Illumina's quality systems and system management processes;
 - (iii) Improved PacBio systems using Illumina's proprietary technologies;
 - (iv) Development of coordinated solutions (including bioinformatics) to enable customers to harness the complementary nature of the Parties' technologies; and
 - (v) Accelerated innovation.
- 2. For the avoidance of doubt, the Parties consider that the Provisional Findings ("PFs") contain important errors that undermine the SLC findings. The Parties will make a separate submission in response to the PFs. The CMA ought to consider the Parties' representations on these points before deciding whether there is an SLC that requires remedy. These representations will also be relevant to the assessment of the appropriateness and proportionality of the proposed remedies.
- 3. Contrary to the statement in the NPR, prohibition is not the only comprehensively effective solution to address the SLC provisionally found by the CMA. Illumina's remedy proposal described below is a sufficient package that removes any SLC whilst preserving the RCBs.
- 4. Further, prohibition would not be a proportionate or "*reasonable and practicable*" (under section 36(3) Enterprise Act 2002) solution. Further, the RCBs identified are significant in scale and nature, and the CMA should take into account the RCBs that would be lost as a result of a prohibition. All RCBs would be lost if the Transaction were to be prohibited.
- 5. As further discussed in **Annex 1**, Illumina proposes the following alternative undertakings to remedy the SLC provisionally identified by the CMA:
 - (i) A perpetual, royalty-free, irrevocable, sole licence of PacBio's patents listed in **Annex 1** to Oxford Nanopore Technologies ("ONT"); or

¹ See paragraphs 426 to 459 of the Merger Notice.

- (ii) A perpetual, royalty-free, irrevocable, licence of PacBio's patents listed in **Annex 1** to any interested third-party undertaking for use in the nanopore field.
- 6. The CMA Merger Remedies Guidelines recognise that an exclusive, irrevocable, and royalty-free technology licence "*will effectively be treated by the CMA as structural in form and subject to similar consideration and evaluation as an asset divestiture*",² and each of the undertakings proposed above would be sufficient on its own to remedy the SLC provisionally identified by the CMA in its PFs.
- 7. A perpetual, royalty-free, irrevocable, sole licence of PacBio's patents listed in **Annex 1** would enable ONT to further improve its native long read systems offering. While ONT has technological and competitive advantages over PacBio, one significant perceived weakness of its technology is the accuracy of its systems. All of the patents offered for licence to ONT in this proposal entail methods that improve accuracy. In particular many of the patents cover methods of single-molecule consensus sequencing. A license of the patents listed in **Annex 1** would enable ONT to become a significantly stronger competitor in various ways:
 - (i) First and with almost immediate effect, it would enable ONT to commercialise its 2D products which it has agreed to refrain from offering in certain European countries until 2023 as part of a settlement of patent infringement lawsuits alleging infringement of one or more of the patents identified in Annex 1.³ Reports from the Genome Sciences meeting in Edinburgh in September 2019 indicate that ONT has a new proven-to-work version of 2D chemistry ready to be brought to market in a matter of weeks.
 - (ii) Second, the licenses would remove the threat of an injunction potentially preventing the sale of all ONT sequencing products in the U.S.⁴
 - (iii) Third, the licenses would enable ONT to improve the accuracy of all of the instruments that ONT currently markets and to develop and market new products without fear of litigation regarding these technologies. The patents offered to ONT or to third parties in paragraph 5 above, for instance, include patents for base calling using n-mers (as opposed to calling individual bases). ONT's accuracy will be significantly affected if it is unable to call bases using n-mers. Likewise, ONT's chief executive has described multiple approaches to single-molecule consensus that ONT is considering but which might be challenged as infringing by PacBio. The licenses being offered would remove the threat of litigation.
- 8. The resulting enhanced competition from ONT will further incentivise the merged entity to continue innovating and improving its systems offering in order to compete for customers seeking native long read functionality.

² Merger Remedies Guidelines, 13 December 2018, paragraph 6.2.

³ See Response to Issues Paper, 27 May 2019, at paragraph 139; Response to Annotated Issues Statement, 24 September 2019, at paragraphs 114 to 117.

⁴ A trial between PacBio and ONT is scheduled to be heard in Delaware in March 2020 on four patents listed in **Annex 1**.

- 9. Further, a licence to ONT would directly address the concerns expressed by the CMA in paragraphs 24 and following of the NPR regarding the appropriateness of an IP remedy in the case at hand. First, ONT is an established player with technical expertise, a developed commercial infrastructure and the potential to raise equity to finance growth from the capital markets in Europe, the United States and Asia (in a way that PacBio does not). It, therefore, has the capabilities to develop and commercialise an improved offering using the licenced patents in order to compete even more effectively with the merged entity on the market for native long read systems. Second, the proposed licence of PacBio's patents is perpetual, which would ensure continued access to the licenced patents. Finally, given that ONT already commercialises a nanopore technology, it would be able to develop and commercialise any products incorporating technology reading on PacBio's patents rapidly.
- 10. A perpetual, royalty-free, irrevocable, licence of PacBio's patents listed in **Annex 1** to third-party undertakings for use in the nanopore field would likewise be a fully effective, reasonable and proportionate undertaking to remedy the SLC provisionally identified by the CMA. Further, this undertaking addresses the concerns expressed by the CMA in paragraphs 24 and following of the NPR regarding the appropriateness of an IP remedy in the case at hand.
- 11. First, by making PacBio's patents listed in **Annex 1** fully accessible to third-party undertakings active in developing nanopore technology, one of the most significant barriers to entry identified by the CMA in its NPFs, *i.e.*, IP, is eliminated.
- 12. Second, the CMA is concerned that "any licensee would need to have sufficient capabilities" in "supporting commercial infrastructure (for example sales and marketing, manufacturing) [...] to effectively compete with the merged entity, which would retain all of these assets".⁵ However, in the pool of potential licensees there are a number of large companies, including Roche (the world's largest biotechnology company and the world leader in IVD and tissue-based cancer diagnostics), Agilent (a leader in life sciences, diagnostics and applied chemicals with almost \$5 billion in revenue and more than 24,000 customers in 110 countries), and NanoString (a provider of life science tools for translational research and molecular diagnostics which has had success commercialising its non-sequencing products), all of which have significant commercial capabilities. For example, Roche will be able to leverage its existing distribution infrastructure, relationships with clinical customers (which are more extensive and well-developed than Illumina's), and its previous experience in supplying sequencing systems.
- 13. Third, the CMA asserts that the potential licensee should be able to leverage "*the potential competitive benefits of existing short read operations*".⁶ In the pool of potential licensees there are companies which are currently offering or developing short read systems, such as BGI, Thermo Fisher, Agilent, and Omniome.

⁵ See paragraph 28 of NPR.

⁶ See paragraph 28 of NPR.

- 14. PacBio has the benefit of a licence from Cornell University in respect of nine U.S. patents, which have in turn been sub-licensed to BioNano.⁷ Save for these licenses-in, PacBio does not believe that it has the benefit of any third party licenses that would be required for ONT or any third party to conduct nanopore sequencing under the claims in the patents and patent applications covered by the offer in paragraph 5 above. PacBio is confident therefore, on the facts, that the concerns set out by the CMA at paragraph 32 of the NPR are unfounded.
- 15. While the Parties reject the provisional SLC findings, either of the proposed remedies will ensure that any potential SLC is eliminated and that the important RCBs are maintained. In contrast, a prohibition would involve a loss of all RCBs and would therefore be unnecessary and disproportionate.

⁷ See PacBio's reply to the CMA's Section 109 notice, 14 August 2019 (consolidated reply), Question 40, page 24.

Annex 1 to Response to Notice of Possible Remedies – Remedy Proposal

- 1. Illumina proposes the following two alternative undertakings to remedy the SLC provisionally identified by the CMA:
 - (i) A perpetual, royalty-free, irrevocable, sole licence of PacBio's patents listed in the Attachment to Oxford Nanopore Technologies ("ONT"); or
 - (ii) A perpetual, royalty-free, irrevocable, licence of PacBio's patents listed in the Attachment to any interested third-party undertaking for use in the nanopore field.
- 2. Illumina also proposes compliance mechanisms to address any concerns that Illumina might be incentivised to breach any of its commitments including: (i) the appointment of a monitoring trustee; and (ii) making a fast-track dispute resolution mechanism open to third parties. The CMA approved monitoring trustee will monitor compliance with the licencing terms and prepare a compliance report every 12 months. The monitoring trustee will also rule on any disputes between the licensee(s) and Illumina under a fast-track dispute resolution process. If a party wishes to appeal a ruling by the monitoring trustee, there will be recourse to a fast-track arbitration procedure. Illumina commits to follow the monitoring trustee/arbitrator's rulings on any disputes and to provide the monitoring trustee with all the information and assistance (including access to confidential documents) as may be reasonably required in order to carry out its mandate effectively.