Illumina's Proposed Acquisition of GRAIL: Accelerating EU Access to Essential Cancer Diagnostics

Introduction

Illumina is a US company that supplies next generation sequencing (NGS) systems for genetic and genomic analysis. Illumina's core mission is to accelerate greater NGS adoption, including bringing genomic testing to under-served communities. Illumina has long pursued this strategy by driving down the cost of sequencing and improving its NGS systems and workflows.

Illumina recently reacquired GRAIL – a cancer screening start-up that it spun out in 2016. GRAIL has developed an early screening test, Galleri, that can simultaneously screen for more than 50 types of cancer in asymptomatic patients, with a single blood test. As Europe's Beating Cancer Plan recognizes, early detection through screening offers the best chance of beating cancer and saving lives.

Illumina aims to accelerate the roll-out of GRAIL's Galleri test in the EU to 2024, which GRAIL alone would not be able to do until after 2030. This acceleration could save the EU close to 100,000 lives and billions of euro in healthcare costs. The merger would therefore have a transformative, positive impact on the EU's health and cancer policy landscape.

Merger review by DG Competition

DG Competition will shortly issue a Statement of Objections in the Illumina / GRAIL transaction (the "Transaction"). This briefing paper aims to provide a summary of the core issues in the Commission's review. It gives a brief background on Illumina and GRAIL, sets out the core policy considerations relevant to the Commission's decision, and addresses key arguments we anticipate that DG Competition will raise.

Reuniting Illumina & GRAIL

Illumina has a long-standing commitment to oncology. It has collaborated with pharmaceutical companies to develop tests to select and target cancer therapies. Since 2019, Illumina is a key partner of the German National Decade against Cancer. Illumina supports Europe's Beating Cancer Plan, and its recognition of the crucial importance of broad, early cancer screening and detection.

GRAIL is a US start-up, formed five years ago when Illumina researchers discovered the potential for a blood test to screen for a wide range of cancers while researching Non-Invasive Prenatal Testing (NIPT). Illumina recognized the potential for such a test to revolutionize the race to detect cancers at all stages. In 2016, Illumina spun GRAIL out so that it could secure the broader investment to develop the technology.

Yet Illumina and GRAIL were never completely separate: Illumina maintained a c. 12% equity stake in GRAIL and was entitled to a percentage of GRAIL's net revenues in perpetuity. The Transaction fully reunites Illumina and GRAIL at a critical juncture.

Bringing GRAIL's Galleri to the EEA Sooner, Saving Nearly 100,000 Lives

The main policy question is how quickly European citizens can benefit from transformative cancer diagnostics that GRAIL has developed. GRAIL's Galleri is a singularly broad screening test that can diagnose 50 cancers at once in asymptomatic patients, and, uniquely, can identify the tissue in which a cancer has developed. Galleri can potentially prevent over a quarter of five-year cancer deaths in those aged over 50. However, on its own, GRAIL does not plan to market its Galleri test in the EEA until after 2030.

The Transaction would enable Illumina to bring that date forward by at least five years. In the EEA, this earlier roll-out would see over 90 million tests and up to 96,000 lives saved between 2025 and 2035. By 2035, Illumina expects to save around 20,000 lives annually in the EEA.

This should also reduce cancer-attributable costs by billions of euro. Thus, the Transaction would yield significant benefits for cancer patients in Europe and relieve stress and cost on healthcare systems.

Galleri's roll-out will transform cancer screening in Europe, and enable improvements in early diagnosis an order of magnitude greater even than those envisaged by the EU's ambitious Beating Cancer Plan. Eastern and Central European Member States currently have the lowest adoption for traditional cancer screening programs (Romania, Bulgaria, Hungary, and Poland), and could see some of the greatest impact.

Illumina's Strong Track Record with NGS-Based Diagnostics in Europe

The policy benefits arising from the Transaction are due to the considerable synergies between Illumina and GRAIL. GRAIL is a young company with no experience of obtaining either regulatory approvals or reimbursement. Illumina is unique in having the experience of both obtaining regulatory and reimbursement approvals for NGS systems and NGS-based blood tests in the US and the EEA. It has a strong track record in the EEA from its roll-out of non-invasive prenatal testing (NIPT) across the continent.

For instance, reimbursement by healthcare payors is key to providing access to this test. In the EEA, reimbursement decisions are made country-by-country. This makes entering the EEA market costly and time-consuming. GRAIL alone is a small startup; it does not have the experience to seek and gain this essential reimbursement. Illumina does.

Rolling Galleri out on Illumina's timetable will also require significant investments in adapting the test to the EU testing lab ecosystem. This is exactly how Illumina helped scale the testing capacity for NIPT in Europe, for the benefit of pregnant women. NIPT provision in the EEA has gone from a handful of tests performed in US labs, to half-a-million tests a year, mostly performed in a decentralized network of labs across the EEA.

Illumina is also committed to making Galleri available in Africa, Asia and Latin America – which, absent the Transaction, would be unlikely to have the benefit of this life-saving test for decades.

These are important merger-specific and verifiable efficiencies that the Commission can and should take into account.

DG Competition's Theory of Harm & Jurisdiction

Unlike the clear benefits outlined above, DG Competition's theory of harm in this case is highly speculative and not supported by the evidence.

DG Competition acknowledges that the Transaction does not involve the merger of competitors, and accepts that it is not a "killer acquisition". DG Competition's concern is that, post-Transaction, Illumina could favor GRAIL and disadvantage GRAIL's potential competitors (so-called "vertical foreclosure").

However, as outlined above, GRAIL's test is unique. In these circumstances, Illumina has no incentive to foreclose any other cancer screening test developer, as doing so will not result in any benefit to GRAIL.

Illumina would in any case not be able to foreclose any future NGS test developer that does develop a test that competes with GRAIL, as there are alternative NGS systems that are comparable in performance and cost to Illumina's. There are also various well-funded efforts to develop new NGS platforms, some of which are run by former Illumina executives with deep experience in NGS. With certain Illumina patents set to expire in the next few years, it is generally accepted by market analysts that Illumina will lose upstream share to such new entrants. There is ample evidence that NGS test developers could switch to these alternative platforms, were Illumina to pursue a foreclosure strategy in the future. On this basis alone, a foreclosure strategy by Illumina is implausible.

Moreover, GRAIL currently has no presence in the European Economic Area (EEA): no research activities, no employees and no plans to enter the EEA for the foreseeable future. Thus, any potential effects on competition in the EEA are remote and speculative. It also raises serious questions about DG Competition's jurisdiction in this case.

Finally, any residual concerns that DG Competition may still have about the merger would be more than comprehensively addressed by the draft remedy commitments that Illumina proposed in Phase I of the Merger review, such as irrevocable supply commitments to customers in the EEA.

Conclusion

In summary, the life and cost saving benefits of this transaction are compelling and should be taken into consideration as the Commission completes its review. Given the complexity and importance of the issues at stake, please feel free to contact us at any time, should you have questions on the above.

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