ILLUMINA/GRAIL—THE DAWN OF A NEW ERA FOR GLOBAL MERGER CONTROL?

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The European Commission's (EC) decision to block Illumina's acquisition of Grail marks the dawn of a new era for acquisitions of startups with innovation potential. This case involved many "firsts": It is the first time that the EC prohibited the acquisition of a U.S. startup with no revenues in the European Union; it is the first time that the EC used the vertical innovation theory of harm to prohibit a merger; and it appears likely it will result in the highest gun-jumping fine ever imposed by the EC under the European Union Merger Regulation (EUMR).[1]

This will inform the review of other acquisitions of innovative startups, particularly by large pharma and tech companies. EC Commissioner for Competition Margrethe Vestager stressed that this case creates "important synergies" with the reporting obligation under Article 14 of the Digital Markets Act,[2] pursuant to which digital gatekeepers will need to inform the EC of all their acquisitions in the digital sector.[3] But, beyond startups, the case is also highly relevant for acquisitions of established companies in oligopolistic markets where innovation plays a key role, as it affirms the EC's policy priority to challenge and even prohibit mergers if they may reduce innovation competition.

We discuss below the key takeaways for dealmakers, and then we dive deeper into the background and timeline of the case, the EC's unlimited jurisdiction under the EUMR, and the EC's novel innovation theory of harm.

KEY TAKEAWAYS

- The EC now has unlimited jurisdiction to review any transaction that can potentially have anticompetitive effects in the European Economic Area,[4] even when the target has zero sales in Europe. The EC now joins the ranks of other jurisdictions, notably the United States, which can challenge a transaction regardless of whether the merger notification thresholds are met. The EC's official guidance singles out the tech and pharma sectors as key focus areas for this unlimited jurisdiction, but the same guidance also contains broader language to cover any other transaction occurring in a sector where innovation is an important parameter of competition.
- A worldwide bar on closing applies from the moment when the EC informs the parties that a referral request has been made.[5] Failure to comply will result in enormous fines. Illumina, who closed the transaction while the Phase II review before the EC was pending, already set aside US$453 million (or approximately 10% of its worldwide turnover) for a possible gun-jumping fine.[6] A gun-jumping fine of this level would significantly exceed the €124.5 million record gun-jumping fine that the EC imposed in 2018.[7]

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- The EC has a wide leeway to challenge mergers based on innovation theories of harm, which are more qualitative in nature compared to traditional price effects cases, and, therefore, much harder to defend for merging parties.
- The EC heavily relies on qualitative assessments drawn from internal documents and views from third-party customers and competitors to build up its case. Particular caution should be paid to document creation and interactions with third party customers and competitors.
- Dealmakers should be particularly careful when they negotiate a sale and purchase agreement (SPA) involving an innovative start-up or an established company that is active in an oligopolistic market where innovation is a key driver. The jurisdictional and substantive risks of Illumina/Grail have a significant impact not only on the provisions relating to antitrust risk allocation (conditions precedent, antitrust covenants to get the deal through, reverse break-up fee, drop dead date), but also on the valuation, and ultimately the feasibility, of the deal.

BACKGROUND AND TIMELINE

Illumina is a U.S. biotech company and a leader in next-generation sequencing systems (NGS). In September 2020, Illumina agreed to acquire Grail, a U.S.-based developer of blood tests for multiple early stage cancers, for US$7.1 billion. Grail was originally formed in 2015 as a subsidiary of Illumina, but Illumina spun it off in 2017 so that Grail could obtain outside investments.

United States	**Date**	**European Commission**
Illumina signs SPA for acquisition of Grail	20 Sept. 2020	
Parties file Hart-Scott-Rodino Act (HSR Act) notice	9 Oct. 2020	
Federal Trade Commission (FTC) issues second request	9 Nov. 2020	
FTC sues to block merger and seeks preliminary injunction	30 March 2021	
	19 Feb. 2021	EC invites Member States to make Article 22 referral
	9 March 2021	France makes Article 22 referral

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United States	Date	European Commission
	31 March 2021	EC publishes new guidance on Article 22 referrals
	19 April 2021	EC accepts referral request and asserts jurisdiction
	28 April 2021	Illumina appeal of EC's decision to assert jurisdiction
FTC withdraws preliminary injunction in light of EU review	20 May 2021	
	16 June 2021	Illumina files Form CO to the EC
	22 July 2021	EC opens Phase II
	18 Aug. 2021	Illumina closes the deal
	20 Aug. 2021	EC opens gun-jumping investigation
	29 Oct. 2021	EC imposes hold-separate interim measures
	13 Jul. 2022	EU General Court upholds EC jurisdiction
FTC administrative law judge (ALJ) rules in Illumina's favor	2 Sept. 2022	
FTC appeals ALJ ruling to commissioners	2 Sept. 2002	
	6 Sept. 2022	**EC blocks Illumina/Grail deal**

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United States	Date	European Commission
	23 Sept. 2022	Illumina appeals EU General Court judgement on Jurisdiction
	28 Oct. 2022	EC renews and adjusts hold-separate interim measures

The timeline in itself is revealing in two ways.

First, the U.S. and EU antitrust review took approximately two years from the signing of the Illumina/Grail SPA. This is almost twice as long as the one-year drop-dead date in the Illumina/Grail SPA. The clear takeaway is that for this type of transaction, it is essential to build-in sufficient flexibility to extend drop-dead dates due to merger review, without triggering the payment of reverse break-up fees.[8]

Second, this case is another example that the antitrust agencies talk to each other. In this particular case, it is clear that the antitrust enforcement in the EC influenced the FTC and vice-versa, both on the procedural and substantive fronts.

- On the procedural front, the timeline shows that the FTC withdrew its motion for a preliminary injunction shortly after the EC asserted jurisdiction over the transaction, on the basis that the Illumina/Grail deal would be subject to the EUMR bar on closing, which is global in scope, and thus that a preliminary injunction was no longer needed in the United States.[9]
- On the substantive front, the EC blocked the deal on a vertical theory of harm similar to that used by the FTC.[10] In both cases, the agencies were concerned that Illumina would foreclose Grail's competitors and their ability to innovate. See further below.

The EC's Unlimited Jurisdiction Under the EUMR

The novelty in the Illumina/Grail case is that the target, Grail, had no revenues in the European Union. Until a couple of years ago, this would have meant that a filing under the EUMR would be ruled out. The reason for this was that the EUMR thresholds are based on turnover thresholds and require each of at least two parties to generate some turnover in the European Union.

Since the Facebook/WhatsApp case in 2014,[11] the EC has been increasingly concerned that the EUMR thresholds were not sufficient to capture so-called “killer acquisitions,” i.e., acquisitions of highly innovative companies whose current turnover is not representative of their competitive significance, carried out by established incumbents in order to take out potential future competition. This led to an EC consultation process in the 2016–2019 period, which was focused on the possible introduction of value-based thresholds. Instead, the EC decided in 2020 to address the “killer acquisition” issue through the referral mechanism already included in Article 22 of the EUMR. Article 22, traditionally known as the “Dutch clause” was designed to enable Member States that did not have a merger control regime—like the Netherlands at the time of the adoption of the original EUMR in 1989—to refer to the EC mergers that potentially raised competition concerns in their territory.

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In her 11 September 2020 speech in Florence, Margrethe Vestager announced that the EC would change its policy and would now accept—or even encourage—Article 22 referrals from Member States whose national merger control thresholds are not met. This new policy was formalized on 26 March 2021 in the EC's Article 22 Guidance.[12] The only two conditions are that the transaction affects trade between Member States, and that it threatens to affect competition within the territory of the Member State making the request.[13]

Less than a month after the Article 22 Guidance was adopted, on 19 April 2021, the EC accepted an Article 22 referral request by France, which was joined by several other Member States (including Belgium, Greece, Iceland, the Netherlands, and Norway).[14]

Illumina challenged the EC's decision to assert jurisdiction on several grounds, notably: (i) the EUMR did not allow for the referral of below-threshold transactions by Member States; (ii) the change in policy constituted a breach of the principle of legal certainty; and (iii) the change constituted a breach of legitimate expectations. The EU General Court, in its 13 July 2022 judgment, fully upheld the EC's decision to assert jurisdiction based on Article 22 of the EUMR.[15] The EU General Court carried out a comprehensive literal, historical, contextual, and teleological interpretation of Article 22 of the EUMR and related provisions, and it concluded that the EC was fully entitled to use the referral mechanism even when the national merger control thresholds are not met.[16] The EU General Court noted in particular that: (i) the question of whether the conditions for the exercise of Article 22 are met is a matter of EU and not national law;[17] (ii) even if the initial objective of Article 22 was to cover referrals from Member States that did not have their own merger control regime, Article 22 did not exclude the ability of Member States that have adopted merger control laws to refer below-threshold concentrations; and (iii) ultimately, the objective of Article 22 was to be an “effective corrective mechanism” to capture transactions that were likely to significantly impede competition in the internal market.[18]

The EC's Innovation Theory of Harm

Innovation was already identified as a key parameter for the EC's competitive assessment in the 2004 Horizontal Merger Guidelines and the 2008 Non-Horizontal Merger Guidelines.[19] Innovation also is one of the criteria in the Horizontal Merger Guidelines to assess whether the merger would eliminate an important competitive force.[20] Despite these references, the EC's merger enforcement until recently focused primarily on price and output.

The first breakthrough of innovation competition as a stand-alone theory of harm was in 2017, when the EC took enforcement action against a global agrochemical merger. In that case, the EC found that while innovation was not a market in its own right, it was an input activity for both the upstream technology markets and the downstream crop protection markets relevant to that merger.[21] The EC looked at the impact of the merger on innovation both at the level of the crop protection industry as a whole, and on certain innovation spaces where the merging parties were “close and important innovation competitors.”[22] These innovation spaces were comprised of groupings of crop protection and pesticide combinations, but they were not properly defined relevant markets.[23] The EC found that the crop protection industry was characterized by “oligopolistic innovation competition” and that a reduction of the global integrated players with Research & Development (R&D) capabilities from five to four would reduce innovation output, and competitors would be unlikely to offset that reduction of innovation output.[24] These concerns led to the divestment of the entire R&D organization for crop protection of one of the merging parties in addition to the divestments required to address more traditional price effects.

The Illumina/Grail decision goes even further by applying the innovation theory of harm to a vertical merger.[25] The EC found that Illumina was dominant in NGS systems and that these systems were an essential input for Grail

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and its downstream competitors. As a result, the concern was that Illumina would have the ability and incentive to foreclose Grail's downstream rivals and favor Grail by: (i) refusing to supply its NGS technology, or (ii) otherwise disadvantaging them through higher prices, reducing access to new technologies, or delaying supplies. These potential foreclosure effects would undermine the ongoing innovation race in the emerging market for blood-based cancer tests, which is expected to reach more than €40 billion by 2035.

The FTC expressed very similar concerns that Illumina, through its NGS platform, would control the fate of every potential rival to Grail for the foreseeable future and would have the ability and incentive to slow the development of any products that could compete with Grail.[26]

The EC rejected Illumina's proposed commitments to address these concerns in the upstream NGS and the downstream blood-testing markets. The reason was that the upstream intellectual property licensing and no-challenge commitments did not guarantee that any of the other NGS suppliers would become a credible alternative to Illumina. The standard contract commitment that Illumina offered to downstream NGS customers was also rejected because it would be very difficult to detect any discrimination in favor of Grail, and it did not cover all possible ways in which Illumina could degrade access to NGS systems. This would, in turn, reduce the ability and incentives of Grail's competitors to continue to invest in the development of these alternative blood-based tests for cancer detection.[27]

The FTC ALJ reached different conclusions in his 2 September 2022 initial decision, finding in favor of Illumina. However, this is not in and of itself indicative of a split in enforcement. The FTC has already appealed that decision to the commissioners, and it is widely expected to reverse the ALJ's decision. Should the commissioners find against Illumina, Illumina can appeal that decision to a panel of federal U.S. judges. Illumina has stated that it is ready to litigate the case all the way up to the U.S. Supreme Court.

CONCLUSION

Illumina/Grail broke new ground both on the jurisdictional and substantive fronts.

- The EC can now assert jurisdiction over any transaction that could potentially affect competition in the European Economic Area. This expansive jurisdictional approach is still subject to judicial scrutiny. Illumina and Grail have already appealed the General Court's judgment before the Court of Justice of the European Union (the highest EU court), while Andreas Mundt, the head of the German Federal Cartel Office (FCO), has indicated that the FCO will not refer below-threshold concentrations until the Court of Justice of the European Union ultimately rules on this jurisdictional issue.
- The EC views innovation rivalry as a key parameter of competition that should be preserved on a precautionary basis, and it will take enforcement action or even prohibit a deal that raises this type of concern.[28] Illumina/Grail marked the first instance where the EC used the innovation theory of harm to prohibit a vertical merger.

While it remains to be seen whether the EU courts will finally uphold the EC's expanded jurisdiction and its expanded innovation theory of harm, the EC will continue to consider Illumina/Grail good law for all future acquisitions. Deal-makers should take into account this risk in their SPA negotiations.

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FOOTNOTES

[1] The EC has already sent a statement of objections against Illumina for the "unprecedented" step of closing the acquisition pending a Phase II review by the EC. *See "Mergers: The Commission alleges Illumina and Grail breached EU merger rules by early implementation of their acquisition,"* 19 July 2022, https://ec.europa.eu/commission/presscorner/detail/en/IP_22_4604.

[2] *See* Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector (DMA). The DMA entered into force on 1 November 2022, but the key provisions concerning digital gatekeepers will start to apply from 2 May 2023. *See* Article 54 of the DMA.

[3] The Digital Markets Act (DMA) is an EC Regulation that shall apply from 2 May 2023. *See* Regulation (EU) 2022/1925 of the European Parliament and of the Council of 14 September 2022 on contestable and fair markets in the digital sector. Article 14 requires all digital platforms that have been designated as "gatekeepers" under the DMA to inform the EC of any intended acquisition of control of any target company that offers core platform services, services in the digital sector, or otherwise enables the collection of data.

[4] The European Economic Area includes the EU 27 Member States, Iceland, Liechtenstein and Norway.

[5] *See* Commission Guidance on the application of the referral mechanism set out in Article 22 of the EUMR to certain categories of cases C(2021) 1959 final (EC Guidance on Article 22), at para. 31.

[6] Illumina Form 10-Q for the Quarterly Period Ended 3 July 2022, at p. 24, https://s24.q4cdn.com/526396163/files/doc_financials/2022/q2/Form-10-Q-FY22-Q2.pdf

[7] Case M.7993 *Altice/PT Portugal* (24 April 2018). On 22 September 2021, the EU General Court upheld the EC's decision to fine Altice and only marginally reduced it from €124.5 million to €118.2 million. *See* The General Court dismisses Altice Europe's action against the Commission decision imposing two fines totalling €124.5 million in connection with the acquisition of PT Portugal (europa.eu)

[8] The Illumina/Grail merger agreement provided for a "reasonable best efforts" covenant on Illumina to get the deal through, which explicitly excluded any divestments, and a reverse break-up fee of US$ 300 million. The conditions precedent included the HSR Act, but they did not include any specific condition precedent for EUMR clearance (Section 7.07). The initial drop-dead date for the agreement was one year (the "Outside Date" was defined as 20 September 2021. See Illumina Form 8-K filed on 20 September 2020, https://sec.report/Document/0000950157-20-001121/

[9] *See* https://www.ftc.gov/news-events/news/press-releases/2021/05/statement-ftc-acting-bureau-competition-director-maribeth-petrizzi-bureaus-motion-dismiss-request

[10] See FTC Complaint, Administrative Part 3 Complaint (ftc.gov)

[11] The transaction did not trigger the EUMR thresholds. Despite its US$19 billion deal value, WhatsApp's EU revenues were below the EUMR thresholds.

[12] Commission Guidance on the application of the referral mechanism set out in Article 22 of the Merger Regulation to certain categories of cases, C(2021)1959 final, (Article 22 Guidance) at para. 11. *See*guidance_article_22_referrals.pdf (europa.eu)

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[13] *See* EC Guidance on Article 22, paras. 13–17.

[14] Iceland and Norway are members of the European Free Trade Association (EFTA), and not the European Union. However, the EFTA member states have the right to join an Article 22 referral request made under the EUMR. See Article 6(3) of Protocol 24 on Cooperation of the EEA Agreement in the Field of Control of Concentrations.

[15] *See* Case T-227/21, *Illumina vs. European Commission* (13 July 2022) at para. 91 (Illumina vs. EC). On 23 September 2023, Illumina appealed the EU General Court's judgment before the Court of Justice of the European Union (Case C-611/22 P for *Illumina v. Commission* and Case C-625/22 P for *Grail v. Commission and Illumina*).

[16] *See Illumina vs. EC* at para. 91.

[17] *See Illumina vs. EC* at para. 156.

[18] *See Illumina vs. EC* at para. 98.

[19] *See* Guidelines on the assessment of horizontal mergers under the EUMR (2004/C31/03) at para. 8; see also Guidelines on the assessment of non-horizontal mergers under the EUMR (2008/C265/07) at para. 10.

[20] *See* Horizontal Merger Guidelines at para. 38.

[21] *See* Case No COMP/M.7938, Dow/Dupont (27 March 2017) (Dow/Dupont) at para. 348.

[22] *See Dow/Dupont* at paras. 348–52, and para. 2012.

[23] *See Dow/Dupont* at para. 352.

[24] *See Dow/Dupont* at paras. 3015 et seq. and in particular para. 3255.

[25] The EC had also challenged the NVIDIA/Arm deal based on a similar vertical innovation theory of harm, but that transaction was eventually abandoned without a prohibition decision. See https://ec.europa.eu/commission/presscorner/detail/en/ip_21_5624.

[26] *See* FTC Complaint, Administrative Part 3 Complaint (ftc.gov)

[27] *See* EC Press Release, "Commission prohibits acquisition of GRAIL by Illumina," 6 September 2022, https://ec.europa.eu/commission/presscorner/detail/en/ip_22_5364.

[28] The EC had also raised similar "vertical" innovation concerns in NVIDIA/Arm, but that deal was eventually abandoned in February 2022.

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