

CLIENT ALERT

Illumina/GRAIL: Split U.S. and EC Decisions Proceed to Appeal

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In a decision announced September 1, 2022, Chief Administrative Law Judge (“ALJ”) D. Michael Chappell dismissed the Federal Trade Commission’s (“FTC”) complaint against Illumina and GRAIL, finding, among other things, that the FTC failed to prove its prima facie case that the acquisition would cause competitive harm and disadvantage competitors.² The European Commission (“EC”) just five days later *prohibited the merger* under the EU Merger Regulation, finding that Illumina would have the “ability and the incentive to engage in foreclosure strategies against GRAIL’s rivals.”³

The FTC Complaint Counsel has appealed the ALJ decision to the Commissioners of the FTC, and briefing is in progress.⁴ Illumina has announced that it intends to appeal the EC decision to the General Court of the European Union for review of the EC’s prohibition decision.⁵

The split ALJ and EC decisions on the likely competitive effects of the same transaction demonstrate that, despite considerable convergence of U.S. and EU merger law, U.S. and European regulators can evaluate the future significance

¹ Vincent G. Palmeri, Law Clerk, assisted in the preparation of this article.

² *In re Illumina, Inc. & GRAIL, Inc.*, Initial Decision at 190–93 (F.T.C. Sept. 9, 2022) [hereinafter [Initial Decision](#)].

³ European Commission Press Release IP/22/5364, Mergers: Commission prohibits acquisition of GRAIL by Illumina (Sept. 6, 2022) [hereinafter [EC Press Release](#)]; see also Willkie Farr & Gallagher LLP, [European Commission Prohibits Illumina-Grail Acquisition](#) (Sept. 19, 2022).

⁴ Complaint Counsel’s Appeal of the Initial Decision, *In the matter of Illumina, Inc. & GRAIL, Inc.*, NO. 9401 (F.T.C. Oct. 4, 2022) [hereinafter [Complaint Counsel’s Appeal Brief](#)].

⁵ Illumina Press Release, [Illumina Intends to Appeal European Commission’s Decision in GRAIL Deal](#) (Sept. 6, 2022).

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of the same facts differently. Although the FTC Commissioners, who authorized the FTC's complaint against Illumina and GRAIL, may reverse the ALJ decision, the parties could appeal the reversal to a U.S. court of appeals.

"Split decisions" between the U.S. and the EC and the UK are not unprecedented and underscore the need for jurisdiction-specific antitrust analyses.⁶

Factual Context and ALJ Decision

Illumina, a DNA sequencing provider, formed GRAIL in 2015 to develop a multi-cancer early detection (MCED) test that used Illumina's next-generation sequencing ("NGS") as an essential input. GRAIL's MCED test is a noninvasive, liquid biopsy test that screens asymptomatic patients for 50 types of cancer.

The FTC's Complaint Counsel argued that Illumina's acquisition of GRAIL "has a reasonable probability of substantially lessening present and future competition in the research, development, and commercialization of MCED tests."⁷ The FTC asserted that it could satisfy its prima facie burden by showing that "Illumina has an ability and incentive to take action to harm Grail's rivals post-Acquisition."⁸

ALJ Chappell rejected the FTC's "ability and incentive" argument, describing it as a "minimalist formulation . . . unsupported by applicable legal precedent."⁹ According to the ALJ decision, a violation of Section 7 of the Clayton Act requires a multifactor analysis of factual evidence submitted to the record, not just an economic evaluation of "ability and incentive."¹⁰ The ALJ dismissed the FTC's complaint because (1) the acquisition did not give Illumina the ability actually to foreclose (harm) competitors that it did not already have; (2) Illumina did not have a meaningful incentive to harm GRAIL's rivals; and (3) the FTC did not support its argument that the acquisition would create barriers to entry.¹¹

⁶ In 2021, after securing approval from the EC, the proposed merger of Aon and Willis Towers Watson was terminated by the parties when the U.S. Department of Justice challenged the deal. See Alwyn Scott & Sohini Podder, [Aon, Willis halt \\$30 bln merger over monopoly concerns, delay](#), REUTERS (July 26, 2021). In 2019, the UK blocked the merger of Sabre and Farelogix only two days after a U.S. District Court approved the transaction. See J. Bruce McDonald & Mackenzie Rastello, [The Future of Airline Booking: A Bumpy Ride for the Sabre-Farelogix Merger](#), AMERICAN BAR ASSOCIATION. And, in 2001, the EC blocked the merger of GE and Honeywell despite approval of the deal by U.S. authorities. See European Commission Press Release IP/01/939, [The Commission prohibits GE's acquisition of Honeywell](#) (July 3, 2001).

⁷ [Initial Decision](#) at 168.

⁸ *Id.*

⁹ *Id.*

¹⁰ *Id.* at 168–169.

¹¹ *Id.* at 191–92.

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Complaint Counsel are contesting the ALJ's rejection of the "ability and incentive" showing as sufficient to meet the FTC's burden to establish a prima facie case of a likely anticompetitive effect.¹² The parties disagree,¹³ which will likely prompt a clarification on that point of law by the FTC and, later, perhaps by a court of appeals.

Conflicting Approaches to Merger Review

ALJ Chappell's findings conflict with those of the EC, particularly concerning the effects on competition and the impact of the acquisition on competitors. While ALJ Chappell held that the acquisition would not harm competition, the Commission found that the merger would "stifle[] innovation."¹⁴

The EC prohibited the merger in part because of an "innovation race" among GRAIL's competitors. In contrast, ALJ Chappell rejected the FTC's arguments of similar competition among GRAIL and its rivals on the ground that competitors' launch timelines were at least five years in the future. ALJ Chappell also found that competitors' prospective tests were not similar to, and would not be reasonably interchangeable with, GRAIL's MCED test.¹⁵

The EC focused on reduced consumer choices for blood-based early cancer detection tests and Illumina's ability to refuse to supply competitors, increase prices, or degrade the quality of supplies.¹⁶ ALJ Chappell instead found that the acquisition would not provide Illumina newfound power to harm competitors, as Illumina had been, prior to the acquisition, the sole viable supplier of the NGS technology needed to develop the MCED tests,¹⁷ and, as described below, credited Illumina's "Open Offer."

Adequacy of Illumina's Open Offer

To allay competitive concerns – and in accord with the trend of defendants' offering "remedies" to courts and customers that regulators have not accepted – Illumina made an "Open Offer" to all its for-profit, U.S. oncology customers that purchase NGS products for oncology tests.¹⁸ The Open Offer, by its terms, cannot be withdrawn for six years, and once signed, would be effective for 12 years, though customers are permitted to unilaterally terminate the relationship at any

¹² [Complaint Counsel's Appeal Brief](#) at 10–11.

¹³ Respondents Illumina, Inc. and GRAIL, Inc.'s Answering Brief to Complaint Counsel's Appeal Brief at 13–14, *In the matter of Illumina, Inc. & GRAIL, Inc.*, NO. 9401 (F.T.C. Nov. 3, 2022) [hereinafter [Respondent's Appeal Brief](#)].

¹⁴ *Id.* at 190; [EC Press Release](#).

¹⁵ [Initial Decision](#) at 143–45.

¹⁶ [EC Press Release](#).

¹⁷ [Initial Decision](#) at 171–72.

¹⁸ *Id.* at 153.

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time.¹⁹ The Open Offer provided a variety of customer protections, sometimes expressed in terms of the services provided to GRAIL, and firewall protection against the improper use of competitively sensitive information.²⁰

The ALJ found that the Open Offer constrained Illumina's ability to (1) withhold or adversely impact supply to rivals, (2) increase prices, (3) decrease quality of service and support, (4) delay or deny access to new technology, (5) advantage GRAIL by developing products specifically for GRAIL, and (6) deny access to critical information and agreements needed for FDA approvals.²¹

On appeal, Complaint Counsel has argued that the Open Offer should be considered as a remedy to an otherwise illegal acquisition and not part of the Complaint Counsel's prima facie case.²² The merging parties support the ALJ's consideration of the Open Offer as part of the Complaint Counsel's prima facie case.²³

The Department of Justice appears to be litigating a similar legal issue – whether defendants' proposed "fix" to competitive concerns should be considered during the government's prima facie case – in the appeal of a district court's denial of a preliminary injunction against the acquisition by UnitedHealth Group of Change, Inc.²⁴

The EC found that the Open Offer did not effectively address all possible foreclosure strategies, including Illumina's ability to circumvent obligations and grant GRAIL preferential treatment.²⁵ It also referenced the difficulty of monitoring commitments made in the Open Offer because of competitors' lack of ability to detect breaches.²⁶

Conclusion

The appeals process in the U.S. and EU confirm that the ALJ decision and the EC prohibition decision are not the last words on Illumina's proposed acquisition of GRAIL. The split between the initial EC/U.S. decisions, however, should remind entities considering transactions with cross-border implications to review possible competitive effects in all jurisdictions affected within their respective analytical frameworks.

¹⁹ *Id.* at 154.

²⁰ *Id.* at 178–79.

²¹ *Id.* at 179–80.

²² [Complaint Counsel's Appeal Brief](#) at 29–30.

²³ [Respondent's Appeal Brief](#) at 27–29; *see also* [Initial Decision](#) at 182, 196–197.

²⁴ We have written on the UnitedHealth Group's acquisition of Change, Inc. [here](#).

²⁵ [EC Press Release](#).

²⁶ *Id.*

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