Class 24 slides

Unit 12: UnitedHealth/Change and Illumina/GRAIL

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UnitedHealth Group®

CHANGE HEALTHCARE

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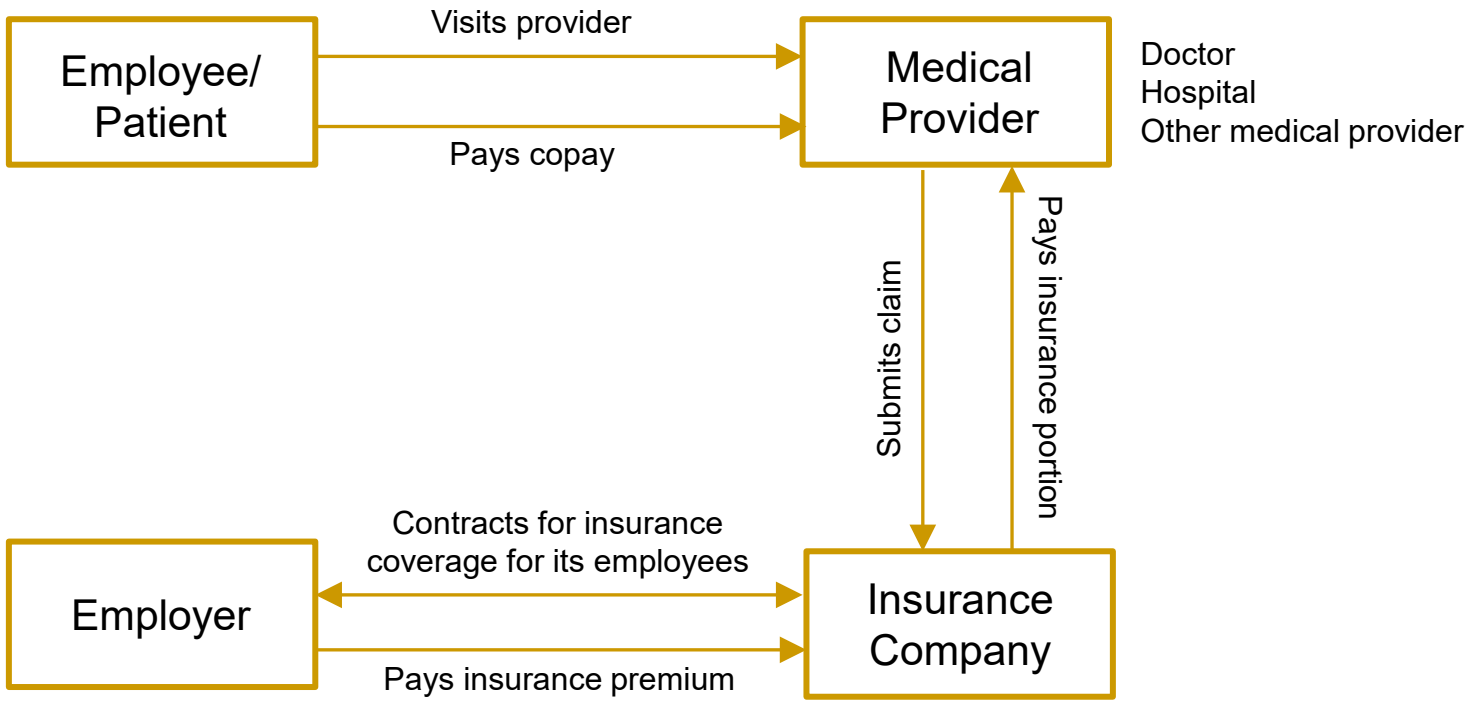
The Health Insurance Process

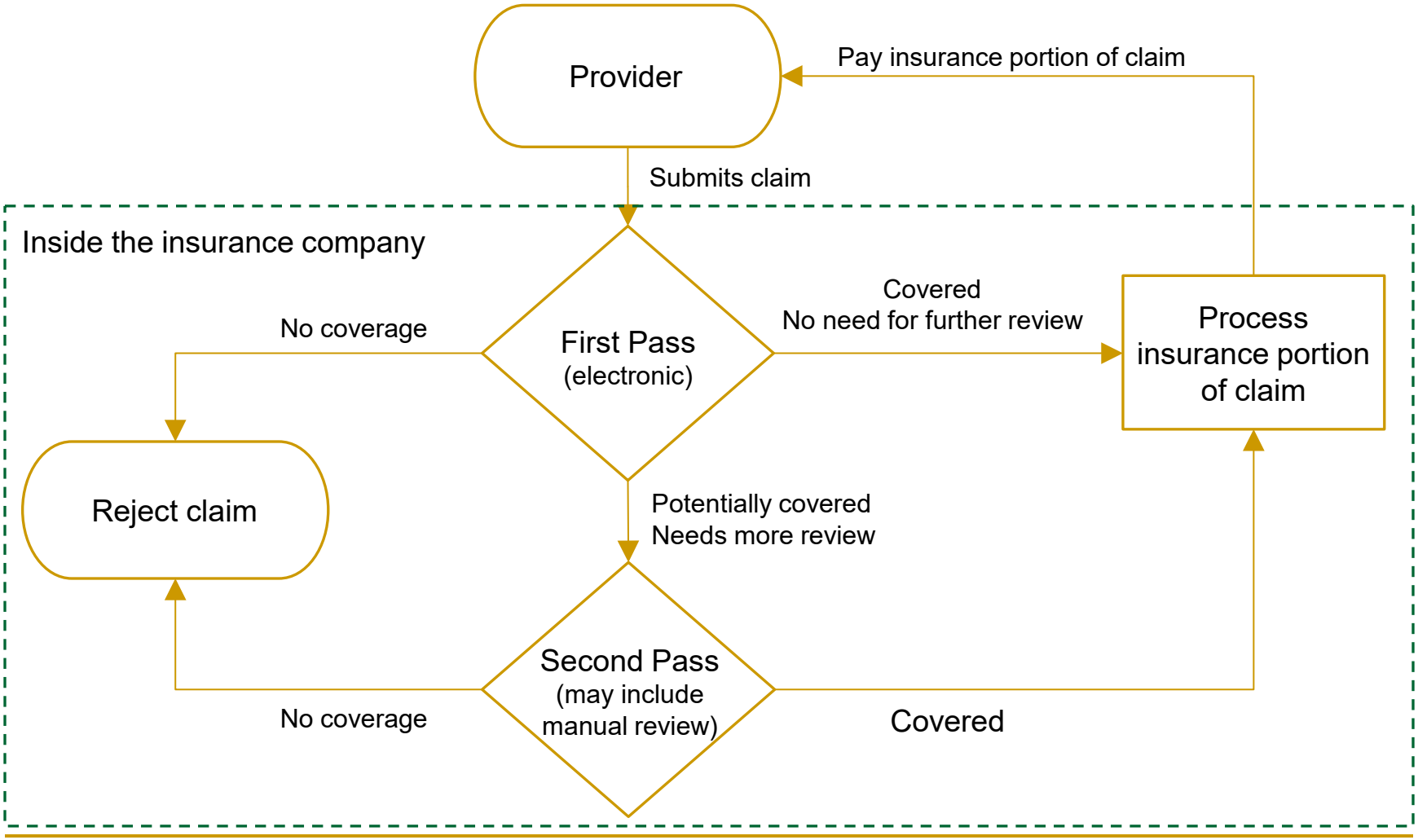
The health insurance payment process

- Overview



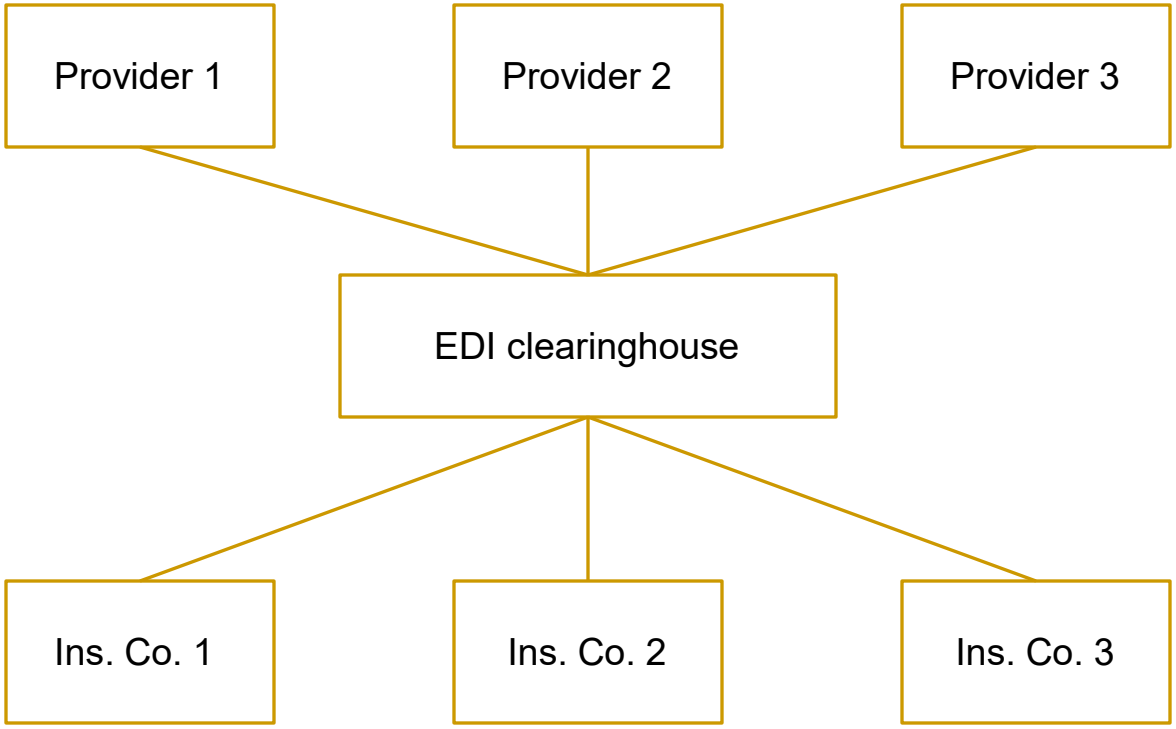
The health insurance payment process

- The “first pass/second pass” claims editing (review) process



The health insurance payment process

- EDI clearinghouses
  - Enable the electronic transmission of claims, remittances, and other information between and among payers and providers



The Deal

The deal

- UnitedHealth Group (UHG) to buy Change Healthcare
  - Merger Agreement signed January 5, 2021 (and announced January 6, 2021)
  - Purchase price: $13 billion
    - $7.84 billion in cash to be paid to Change shareholders
    - Assumption of Change's $5 billion in debt
  - 41% premium over Change's closing price on January 5
  - Drop-dead date
    - Originally January 5, 2022, with an extension to April 5, 2022, if the antitrust conditions have not been satisfied (3 months)
    - Extended on April 4, 2022, to December 31, 2022
      - Added an antitrust reverse termination fee of $650 million in connection with the extension

The parties

- UnitedHealth Group (UHG)
  - UnitedHealthcare (UHC)
    - Nation's largest commercial insurer—covers 50 million people
  - Optum
    - *OptumHealth*: Offers care delivery and management
    - *OptumRx*: Offers pharmacy services
    - *OptumInsight*: Offers healthcare software solutions and services
      - Claims Edit System: Claims editing solution

The parties

- Change Healthcare
  - Software and Analytics
    - Includes ClaimsXten: Market leader in first-pass claims editing
      - 70% market share
      - 99% customer retention
  - Network Solutions
    - Products
      - Facilitates financial, administrative, and clinical transactions
      - B2B and C2B payments
      - Aggregation and analytical data services
    - Provided through Change's EDI clearinghouse
      - Largest EDI clearinghouse in the United States
  - Technology Enabled Services
    - Provides revenue cycle management, value-based care, pharmacy benefits administration, and healthcare consulting

Deal rationale

Benefits of Combination with Change Healthcare

- By combining our products and expertise with those of Change Healthcare, we can increase efficiency and reduce friction in health care, producing a better experience and lower costs.
- Simply put, with this new combination, Optum will help improve the quality of health care delivery, automate claims transactions, and accelerate payment between provider and payer. We will accomplish this through aligning clinical decision making, improving claims accuracy, and simplifying payment.
- The combination of capabilities can improve healthcare by:
  - Helping health care providers and payers better serve patients by more effectively connecting and simplifying key clinical, administrative and payment processes.
  - Promoting better patient outcomes.
  - Reducing the high costs and inefficiencies that plague the health system by improving decision-making processes and putting the right data in the right hands at the right time.
  - Decreasing claims denials. Today, 90% of claim denials are avoidable and create extra work on the back end for everyone involved. By combining with Change Healthcare, we aim to create a system that can help reduce this figure.
- The combination will help us to substantially reduce the estimated $267 billion the U.S. health care industry wastes annually on simply ensuring that health care providers submit valid and properly documented claims and that insurers pay the correct amount for the services provided.
- With the distinct and complementary capabilities and skills of Change Healthcare, Optum will advance anew and more modern foundation to support the next generation health system.

The complaint

- The complaint
  - Filed February 22, 2022
    - After investigating the proposed transaction for more than a year
  - Joined by New York and Minnesota
  - *Venue*: District of Columbia
  - *Relief*: Permanent injunction blocking the transaction

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA
U.S. Department of Justice
Antitrust Division
450 Fifth Street, NW, Suite 4100
Washington, DC 20530,

STATE OF MINNESOTA
445 Minnesota Street, Suite 1400
St. Paul, Minnesota 55101-2131,

and

STATE OF NEW YORK
28 Liberty Street
New York, NY 10005,

Plaintiffs,

v.

UNITEDHEALTH GROUP INCORPORATED
9900 Bren Road East
Minnetonka, MN 55343,

and

CHANGE HEALTHCARE INC.
3055 Lebanon Pike
Nashville, TN 37214,

Defendants.

COMPLAINT

UnitedHealth Group (United), which owns the largest health insurer in the United States, proposes to acquire Change Healthcare (Change), the leading source of key technologies that

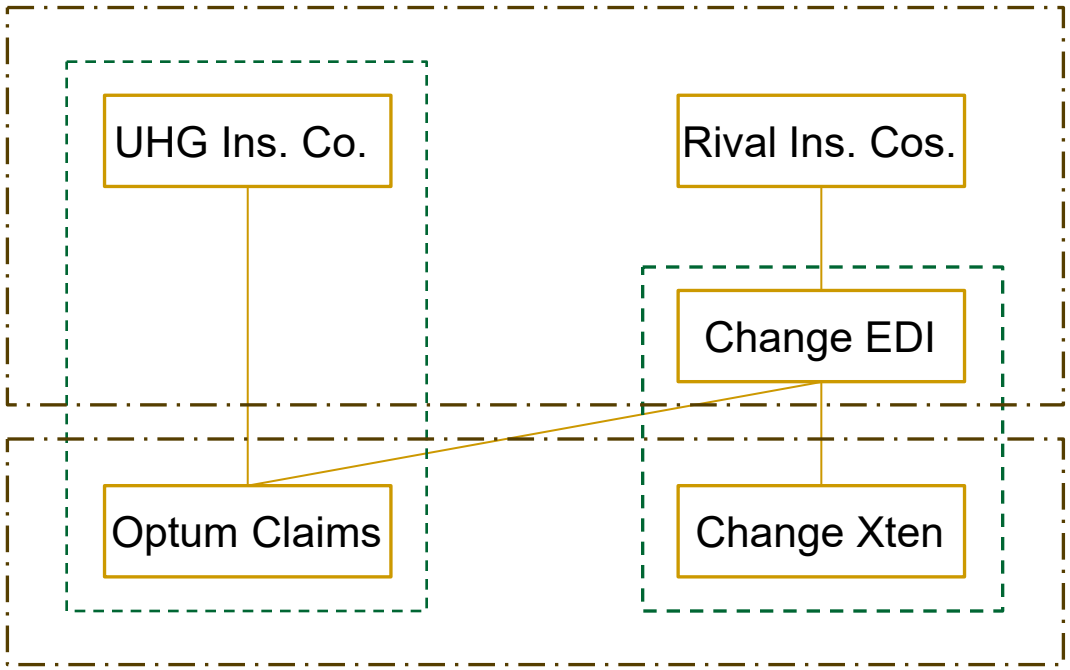
Antitrust claims

1. Horizontal
   - Tend to create a monopoly in the sale of first-pass claims editing solutions in the United States by uniting Optum's Claims Edit System with Change's ClaimsXten

Optum's Claims Editing System	+	Change's ClaimsXten

2. Vertical 1—Anticompetitive information conduit
   - UHG's control over Change's EDI clearinghouse—a key input for UHG competitors—would give UHG the ability and incentive to use rivals' CSI for its own benefit
   - In turn, would lessen competition in the markets for national accounts and large group commercial health insurance
3. Vertical 2—Input foreclosure/RRC
   - UHG's control over Change's EDI clearinghouse would give UHG the ability and incentive to withhold innovations and raise rivals' costs in the markets for national accounts and large group health insurance

Antitrust claims



Input foreclosure
Anticompetitive info. Cond.

Horizontal problem

The trial

- Judge Carl J. Nichols
  - Former partner, Boies, Schiller & Flexner LLP
  - Nominated by President Donald Trump
  - Sworn in: June 25, 2019
- Trial
  - Parties stipulated to a TRO—proceeded to trial on the merits
    - Court consolidated proceedings under Rule 65(a)(2)
  - Trial began on August 1, 2022 (12 days)—5 months after the complaint was filed
    - Over two dozen fact witnesses/1000 exhibits
    - Two expert witnesses from each side
  - Decision: Permanent injunction denied on Sept. 19, 2022
    - Seven months after the complaint was filed
  - Deal closed on October 3, 2022

Experts: DOJ

- Benjamin R. Handel
  - Associate Professor of Economics, Berkeley
  - Consulting Expert, Cornerstone Research
  - Ph.D. Economics, Northwestern University (2010)
  - ASHEcon Medal (top health economist under 40)

- Gautam Gowrisankaran
  - Professor of Economics, Columbia University
  - Senior Advisor, Cornerstone Research
  - Ph.D., Economics, Yale University (1995)
  - Experienced testifying expert

Experts: Merging parties

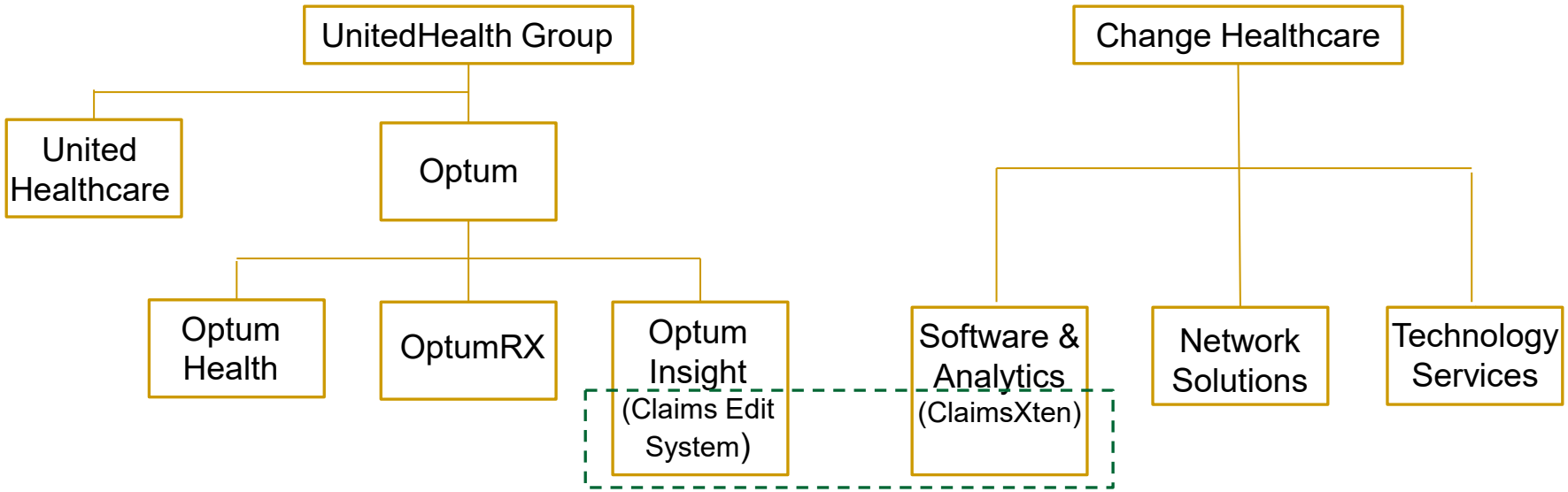
- Catherine E. Tucker
  - Sloan Distinguished Professor of Management Science and Professor of Marketing, MIT Sloan School of Management
  - Academic affiliate with Analysis Group
  - Ph.D., economics, Stanford University (2005)
  - Experienced testifying expert

- Kevin M. Murphy
  - George J. Stigler Distinguished Service Professor of Economics, University of Chicago Booth School of Business
  - John Bates Clark Medal/MacArthur Fellow
  - Ph.D., economics, University of Chicago (1986)
  - Academic affiliate with Charles River Associates
  - Expert witness in numerous antitrust cases

Horizontal overlap in first-pass claims editing

- The gravamen of the complaint
  - Relevant market: First-pass claims editing solutions in the United States
  - Merger to monopoly
    - Change's ClaimsXten (70%) + Optum's Claims Edit System (25%)
    - Delta: 3577
    - Postmerger HHI: 8831
  - Unilateral effects: Eliminate "intense competition" between the two systems

Merging parties do not dispute



Horizontal overlap in first-pass claims editing

- The merging parties' response: Litigate the fix
  - On April 22, 2022, UHG agreed to sell Change's ClaimsXten business to TPG Capital for $2.2 billion
    - Includes all of Change's four claims editing products, which comprise Change's entire primary and secondary claims editing businesses
    - Divestiture contingent on the closing of the UHG/Change transaction and would take place immediately after that closing
      - So UHG would divest ClaimsXten to TPG Capital even if UHG won on the merits

CLAIMSXTEN

Horizontal overlap in first-pass claims editing

- The standard of review: What is the "transaction" under court review?
  - Government's position:
    - Evaluate the original merger: treat the ClaimsXten divestiture as a remedy to an unlawful transaction
    - Defendants must prove the divestiture "maintain[s] the premerger level of competition"
  - UHG's position:
    - The challenged "transaction" is merger with the "fix" in place
    - Government must prove that the merger as modified (including the divestiture) is likely to substantially lessen competition
  - Judge Nichols:
    - Expressly embraces UHG's view; criticizes the "restore premerger competition" standard as inconsistent with "substantially" in Section 7 and with *Baker Hughes*

Horizontal overlap in first-pass claims editing

- A preliminary question: The burden of proof
  - DOJ's position
    - Once the DOJ has proved a prima facie case against the transaction as originally structured, the burden shift to the merging parties to show that the divestiture "will replace the competitive intensity lost as a result of the acquisition"
    - At times suggests that the merging parties bear the burden of persuasion
  - Merging parties' position
    - Since UHG will never acquire ClaimsXten, the government must prove its prima facie case against the restructured transaction, not the original transaction
    - In any event, the DOJ bears the ultimate burden of persuasion under Step 3 of *Baker Hughes* that the restructured transaction violated Section 7

Horizontal overlap in first-pass claims editing

- A preliminary question: The burden of proof
  - Court
    - DOJ's position does find some support in D.C. case law
    - BUT contradicts the language of Section 7 and *Baker Hughes*
      - Section 7 requires that the transaction "*substantially* . . .lessen competition," which is different from the burden the DOJ urges, which would require the merging parties to show that the fix completely replaces the competition lost as a result of the transaction
      - Step 3 of *Baker Hughes* places the ultimate burden of persuasion on the plaintiff
      - The DOJ's version would permit the government to prove its case using the *PNB* presumption and evidence about a transaction that will never happen if the merging parties fail to meet their burden in Step 2 (what it is)
        - The DOJ would never have to show that the restructured transaction was anticompetitive
    - Although the merging parties' position is the better one, the same result obtains in this case under the DOJ's proposed standard

So the court proceeded to analyze the transaction under the DOJ's proposed standard

Horizontal overlap in first-pass claims editing

Court*: Using the DOJ's proposed standard of proof*

1. The DOJ's prima facie case on the original transaction
   - *Relevant market*: The sale of first-pass claims editing solutions in the United States
   - Market shares and participants
     - Change's ClaimsXten: 70%
     - Optum's Claims Edit System: 25%
   - The *PNB* presumption—Easily triggered
     - Combined share: 95%
     - Delta: 3577; postmerger HHI: 8831
   - Explicit theory of anticompetitive harm: Unilateral effects/merger to monopoly

Parties do not contest

The Court finds that the DOJ has satisfied its burden to make out its prima facie case

Horizontal overlap in first-pass claims editing

Court*: Using the DOJ's proposed standard of proof*

2. Assessing the "fix": Five factors—
   a. Likelihood of divestiture: "Virtual certainty"
   b. Experience of TPG (the divestiture buyer)
   c. Scope of divestiture
   d. Independence of TPG
   e. Adequacy of the purchase price

Remember, although the Court preferred assessing the adequacy of the divestiture by asking whether it will preserve sufficient competitive intensity so that the transaction is not likely to substantially lessen competition, it applied the DOJ's approach of whether the divestiture will perfectly restore premerger competitive conditions

Horizontal overlap in first-pass claims editing

Court: *Using the DOJ's proposed standard of proof*

2. Assessing the "fix": Five factors—
   a. Likelihood of divestiture: "Virtual certainty"
      - The parties have a definitive purchase and sell agreement
      - All conditions precedent have been satisfied, except for those to be satisfied at closing or by the resolution of this lawsuit
      - The DOJ does not contest
   b. Experience of TPG (the divestiture buyer)
      - One of the world's leading PE firms, with over $100 billion in assets under management
      - Investment strategy: "We make money from growing the businesses that we invest in"
      - Has significant experience and success with "carve-out" investments
      - Has significant experience in the healthcare industry
        - Has deployed over $24 billion in total equity in the healthcare space
        - Holds healthcare businesses on average for eight years before exiting
      - Intends to invest substantially in the ClaimsXten business
        - Change 2022 budget for ClaimsXten R&D: $14 million
        - TPG plans to increase this to $17 million in 2023, $26 million in 2024, $28 million in 2025, and $30 million in 2026
      - No reason to believe that TPG will not be an adequate divestiture buyer because it is a PE firm

Horizontal overlap in first-pass claims editing

Court: *Using the DOJ's proposed standard of proof*

2. Assessing the "fix": Five factors (con't)—
   c. Scope of divestiture
      - Credits TPG: ClaimsXten is a "a highly separable asset" capable of succeeding on its own was based on extensive due diligence, including conversations with ClaimsXten customers who explained that the product "was sold very independently to the market"
      - ClaimsXten was sold as a standalone product before Change acquired it in 2017
      - Will include a large team of individuals with extensive experience managing ClaimsXten (including the person who will be CEO of ClaimsXten)
      - 375 people will transfer, including—
        - 70-member clinical content team
        - 60-person software and engineering team
        - 200-person customer-success team
   d. Independence of TPG
      - Independent buyer/independent competitor
      - Testimony that TPG will compete vigorously with UHG in first-pass claims editing solutions
        - No evidence to the contrary

Horizontal overlap in first-pass claims editing

Court*: Using the DOJ's proposed standard of proof*

2. Assessing the "fix": Five factors (con't)—
   e. Adequacy of the purchase price
      - To ensure that the divestiture buyer has enough "skin in the game" to provide it with a sufficient incentive to survive in the business and compete vigorously
      - No evidence to doubt adequacy of the purchase price ($2.2 billion)

Horizontal overlap in first-pass claims editing

Court: *Using the DOJ's proposed standard of proof*

3. Court's conclusion
   - *Under the DOJ's proposed standard*:
     - Evidence on the TPG package (scope, assets, personnel, incentives, price) is sufficient to rebut the prima facie case

> Indeed, the trial evidence shows—and the Court concludes—that competition in the post-divestiture market for first-pass claims editing will match, and perhaps even exceed, its current levels.

   - *Under the Court's standard*:
     - Considering merger minus the divestiture business as the "transaction," the Government never establishes its prima facie case that the transaction is likely to substantially lessen competition

Horizontal overlap in first-pass claims editing

Court*: Using the DOJ's proposed standard of proof*

3. Result
   - *Order*: UHG ordered to divest ClaimsXten as proposed
     - *Note:* A court order of divestiture exempts the transaction from the reporting and waiting period requirements of the HSR Act[1]
     - *Query*: If the court rejected the DOJ's claim and found for the defendants, what is the court's jurisdiction to issue the divestiture order?
       - One possibility: The All Writs Act:

> The Supreme Court and all courts established by Act of Congress may issue all writs necessary or appropriate in aid of their respective jurisdictions and agreeable to the usages and principles of law.[1]

[1] 28 U.S.C. § 1651(a).

Vertical anticompetitive information conduit

- DOJ's theory: Four steps—
  1. The acquisition will give Optum access—via the Change EDI clearinghouse—to competitively sensitive claims information (CSI) belonging to rival health insurance companies
  2. Optum will have the incentive to share competitive insights from the CSI with UHC
  3. Knowing this, UHC's rivals will innovate less because of the fear that UHC will free ride off their claims-related innovations
  4. Less innovation → harm to competition in the relevant insurance markets

Note: This theory depends on how rivals would react *to the possibility that UHC would access and use their competitively sensitive claims data to their competitive disadvantage*

NOT how in fact UHC postmerger would use their competitively sensitive claims data to competitively disadvantage them

Vertical anticompetitive information conduit

- The evidence
  - On sharing data
    - Evidence not to share or use rival competitively sensitive claims data
      - Optum currently has access to rival competitively sensitive claims data through its Claims Edit System, which it does not share with UHC
        - Contrary to UHG's entire business strategy and corporate culture
        - Would intentionally violate or repeal longstanding firewall policies
        - Would flout existing contractual commitments
        - Would sacrifice significant financial and reputational interests
    - Rival insurance companies testified that—
      - Optum has strong incentives to comply with the firewalls and protect customers' data, and
      - They trust Optum not to share their data with UHC after the merger
    - The Government offered no conflicting testimony at trial
  - On innovation by rival health insurance companies
    - DOJ failed to adduce evidence that any UHC rival would innovate less out of fear that UHC would access and use their competitively sensitive claims data
      - All payer witnesses testified to the contrary

Vertical anticompetitive information conduit

- Court's conclusion: The DOJ failed to make out a prima facie case
  1. Finding:

> [T]he evidence at trial established, and the Court finds, that United will have strong legal, reputational, and financial incentives to protect rival payers' CSI after the proposed merger.[1]

  2. The DOJ failed to present evidence to show—
     - How much incremental rival CSI would UHG obtain as a result of the acquisition that it would not have through its Claim Edit System, *and*
     - That this incremental information would reverse UHG's premerger profit-maximizing incentive to protect its rivals' CSI and not share it with UHC
  3. The DOJ's allegation that rivals would innovate less was—
     - Based on the speculation of its expert witnesses without supporting real-world evidence
     - Contrary to the testimony of all payers at trial

[1] United States v. UnitedHealth Grp. Inc., No. 1:22-CV-0481 (CJN), 2022 WL 4365867, at *23 (D.D.C. Sept. 21, 2022).

Vertical anticompetitive information conduit

- Court's conclusion: The DOJ failed to make out a prima facie case
  3. Even if payers would innovate less, the DOJ failed to show that the reduced pace of innovation would *substantially* lessen competition:

> The Government rests on the axiomatic truth that payers who are innovating less are also competing less. But it made no attempt to show that the lessening of innovation and competition would be substantial. In fact, the Government's own expert admitted that rival insurers would still innovate after the proposed merger. But establishing that the proposed merger would "lessen innovation" (and thus competition) and that insurers would have "less of an incentive to innovate" (and thus compete) does not establish that the proposed merger would *substantially* lessen competition. The Government failed to offer evidence demonstrating that that standard is met here. But the Court need not rest its holding on this point, as the Government failed to establish other steps in its theory.[1]

Although dictum, this focus of a "substantial" lessening of competition is a significant precedent

[1] United States v. UnitedHealth Grp. Inc., No. 1:22-CV-0481 (CJN), 2022 WL 4365867, at *6 (D.D.C. Sept. 21, 2022).

Vertical anticompetitive information conduit

- Conclusion: The DOJ failed to make out a prima facie case
  4. Central weakness in the government's case
     - The DOJ presented opinion evidence by economic experts without any real-world support
     - The merging parties presented contrary evidence by knowledgeable and experienced party and rival representatives who worked in the business
     - Plus: The Court faults DOJ for not quantifying:
       - the incremental CSI UHG would gain from Change (vs existing Optum data), *and*
       - how that increment would plausibly flip UHG's incentives and lead to substantial competitive harm in the insurance markets

> The evidence at trial highlighted weaknesses in each of these steps. But the central problem with this vertical claim is that it rests on speculation rather than real-world evidence that events are likely to unfold as the Government predicts. Governing law requires the Court to "mak[e] a prediction about the future," and that prediction must be informed by "record evidence" and a "fact-specific showing" as to the proposed merger's likely effect on competition. Under this standard, "antitrust theory and speculation cannot trump facts.[1]

[1] United States v. UnitedHealth Grp. Inc., No. 1:22-CV-0481 (CJN), 2022 WL 4365867, at *6 (D.D.C. Sept. 21, 2022) (quoting United States v. AT&T, Inc., 310 F. Supp. 3d 161, 190 (D.D.C. 2018) (internal citations omitted), *aff'd*, 916 F.3d 1029 (D.C. Cir. 2019)).

Vertical foreclosure

- DOJ's theory: Three steps—
  1. Optum and Change are the only two firms developing an "integrated platform" for payers
     - The integrated platform concept envisioned combining:
       - EDI clearinghouse functions (electronic claims transmission)
       - Payment integrity/claims editing tools (like ClaimsXten)
       - Real-time adjudication capabilities
       - Clinical data integration
     - The goal was to create an end-to-end, streamlined system that would reduce administrative friction, accelerate provider payments, and integrate clinical outcomes data with claims processing
  2. If UHG acquires Change, it would control the development of the only integrated platform
  3. UHG would then foreclose access by UHC rivals by withholding or delaying sales of the integrated platform

Vertical foreclosure

- The evidence
  - The “integrated platforms” in question are only concepts, not products
  - Optum has never withheld a product from UHC’s rivals
    - Optum currently markets all its payment integrity products to UHC’s biggest rivals
  - Optum has never sold one version of a product to UHC and a degraded version to other customers
    - Although Optum has piloted some products with UHG to test them before making them commercially available

Vertical foreclosure

- DOJ's expert testimony
  - Dr. Gowrisankaran's "vertical math" shows that UHG could increase its profits by foregoing sales of its integrated platform (once developed) to rivals
    - The profit losses from not selling the platform to UHC rivals would be more than offset by—
    - The profit gains from insurance sales that would shift from UHC's rivals to UHC's (presumably) better priced commercial insurance products
  - BUT the Court treated executive testimony about the multipayer strategy, and its characterization of foreclosure as fiduciary "nonsense," as more probative than the Government's vertical math:

> Dr. Gowrisankaran's testimony, however, is at odds with the unrebutted testimony of various United executives, who stated consistently their view that it is not in United's interests for Optum to abandon its multi-payer strategy. . . . The Court concludes that this testimony [by Andrew Witty, the CEO of UHG]—and the similar testimony of a number of other United executives—is far more probative of post-merger behavior than Dr. Gowrisankaran's independent weighing of costs and benefits.[1]

The DOJ failed to make out a prima facie case

[1] United States v. UnitedHealth Grp. Inc., No. 1:22-CV-0481 (CJN), 2022 WL 4365867, at *27 (D.D.C. Sept. 21, 2022).

Current status

- Final Judgment entered on September 19, 2022
  - Denying DOJ's request for a blocking injunction
  - Ordering UHG to divest ClaimsXten to TPG Capital as proposed
  - Entering final judgment for the defendants
- Parties closed the transaction on October 3, 2022
  - The DOJ did not request a stay pending appeal
- The DOJ filed its notice of appeal on November 18, 2022
  - Normally, the time to appeal is 30 days after the filing of the final judgment
  - 28 U.S.C. § 2107(b) provides a 60-day period when one of the parties is a U.S. agency
  - DOJ files NOA on the last day permitted by Section 2701(b)
- Parties filed a Joint Stipulation of Dismissal of the appeal on March 20, 2023
  - Essentially no docket activity for four months

UnitedHealth/Change: Why it matters

- Clarifies (and arguably redefines) how integrated divestitures fit into prima facie and rebuttal under *Baker Hughes*
  - But see *Illumina/GRAIL*
- Raises the evidentiary bar for vertical & data-misuse theories
  - "[A]ntitrust theory and speculation cannot trump facts" deployed against well-accepted mechanisms
  - Here, Court-credited facts rebut theories of—
    - Information-misuse conduit
    - Foreclosure/raising rivals' costs
    - Innovation chilling
- Shows a court openly preferring—
  - structural + narrative evidence from defendants
  - over uncorroborated expert modeling by the agencies
- Serves as a playbook for defense counsel on—
  - Designing fixes
  - Using PE buyers
  - Building a multipayer/firewall narrative

Suggests need for corroboration of model conclusion as well as model inputs

A Postscript: Illumina/GRAIL


illumina


GRAIL

The parties

- Illumina
  - Global leader in next-generation sequencing (NGS) instruments and consumables used in genomic research and clinical testing
  - Dominant supplier of sequencing platforms used by all developers of multi-cancer early-detection (MCED) blood tests
  - Generates substantial recurring revenues from consumables, reagents, and service contracts tied to its proprietary sequencing systems
  - Historically operated as a neutral input provider—its business model depends on broad adoption of its NGS technology by multiple downstream developers

The parties

- GRAIL
  - Focus
    - Development and commercialization of multi-cancer early-detection (MCED) tests using Illumina's NGS platform
    - Prior to the merger, GRAIL was one of several MCED developers competing to bring the first broadly approved test to market
  - History
    - Founded by Illumina in 2015 after Illumina unexpectedly discovered cancer signals in prenatal testing
    - Spun it out in 2016 to pursue outside investment focused on liquid biopsy and MCED development, especially Galleri
    - Then reacquired by Illumina in 2021 for roughly $8 billion
  - Flagship product: Galleri
    - A blood test marketed as capable of detecting over 50 cancers through genomic sequencing
    - The only MCED product that has been commercialized

The deal

- Illumina reacquisition of GRAIL
  - Announced September 21, 2020 – Closed on or around August 18, 2021
  - Valued at approximately $8 billion
    - $3.5 billion in cash plus $4.5 billion in Illumina common stock to GRAIL shareholders
      - GRAIL shareholders to hold roughly 12 percent of Illumina's common stock.
    - Contingent value rights (CVRs) providing additional payments based on future performance of GRAIL's MCED test Galleri.
  - Strategic rationale
    - Reintegrate GRAIL's MCED test development with Illumina's sequencing technology to accelerate commercialization and expand cancer screening markets

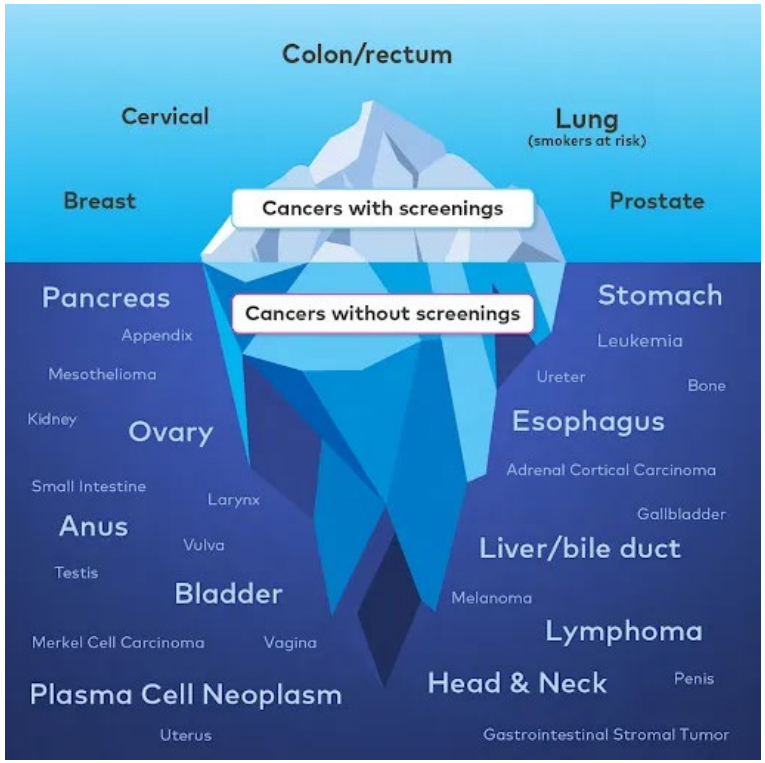
The reacquisition made headlines due to vertical integration between the only viable NGS platform supplier and the only commercial MCED developer, when all MCED developers were dependent on Illumina's technology

The technology

- Next-generation sequencing (NGS) technology
  - NGS enables rapid, high-volume decoding of genetic material by reading millions of DNA fragments in parallel, making it vastly faster and cheaper than previous sequencing methods
- Multi-cancer early detection (MCED) tests
  - Blood-based tests that screen for signals from multiple types of cancer in a single sample, often by detecting cancer-derived DNA, RNA, or proteins shed into the bloodstream
  - Depends on NGS technology to rapidly and accurately detect and analyze tiny amounts of complex cancer-related genetic material from blood samples
    - Not feasible with older sequencing or laboratory techniques
  - MCED tests are viewed as a potential breakthrough because they offer the promise of detecting many types of cancer at earlier, more treatable stages—using a single blood test—potentially saving lives and expanding screening to cancers that currently lack any recommended early detection method

The technology

- Multi-cancer early detection (MCED) tests
  - Only 5 types of cancer have recommended large-scale screening tests (all non-MCED)
  - MCED tests have the potential to detect dozens of additional cancers for which no recommended screening methods exist, expanding early detection to cancers that are typically only found at advanced stages.



The technology

- Multi-cancer early detection (MCED) tests
  - Blood-based tests that screen for signals from multiple types of cancer in a single sample, often by detecting cancer-derived DNA, RNA, or proteins shed into the bloodstream
  - Depends on NGS technology to rapidly and accurately detect and analyze tiny amounts of complex cancer-related genetic material from blood samples
    - Not feasible with older sequencing or laboratory techniques
  - As technology advances and economies of scale develop, MCED tests have the potential to become sufficiently inexpensive for large-scale population screening
    - Would make feasible to routinely test adults for dozens of actionable cancers in a single blood draw
    - As of 2025, however, GRAIL's Galleri test costs $1185.00 and broad insurance coverage is limited

The commercial landscape in 2021

- NGS technology
  - Illumina was the only viable commercial supplier of next-generation sequencing (NGS) platforms capable of supporting MCED blood tests, with all current MCED developers technically and commercially dependent on Illumina's sequencing systems for test launch and scaling

illumina NovaSeq 6000dx
Flagship NGS sequencer for MCED tests

The commercial landscape in 2021

- MCED tests
  - Growing rapidly
    - Globally: Over $400 million
    - U.S.: Over $180 million
  - Commercial suppliers in the United States: Only GRAIL
    - Launched Galleri in Q2 2021 as a prescription laboratory developed test (LDT)
      - Allows earlier clinical use of innovative tests under the Clinical Laboratory Improvement Amendments (CLIA)—not full FDA approval
      - As of 2025, GRAIL's Galleri test is undergoing registrational, large-scale, population-based clinical trials equivalent to FDA Phase III for devices.
    - Began initial availability through partner health systems such as Providence
  - In development
    - Multiple companies in the development stage for MCED tests
      - E.g., Exact Sciences, Freenome, Guardant Health, Natera, Helio Health, Singlera Genomics
    - But none has yet begun the formal FDA approval process
    - Commercial products years away

Antitrust timeline

- The deal
  - Illumina announces intent to acquire GRAIL for $8 billion
  - Files the required HSR premerger notifications (October 9, 2020)
  - Receives a “second request” for additional information from the FTC (November 2020)
- FTC challenge
  - FTC votes to challenge the merger and files an administrative complaint (March 30, 2021)
    - HSR Act waiting period requirements had expired
  - FTC files Section 13(b) complaint to preliminarily enjoin the closing pending completion of administrative litigation (March 31, 2021)
- EC action
  - European Commission accepts Article 22 referral (April 20, 2021)
    - EU Merger Regulation Imposes a “suspense period” during which Illumina is prohibited from closing the transaction
    - This was a controversial application of Article 22 that extended EU merger jurisdiction to a U.S.-only deal based on competition concerns raised by multiple member states, despite GRAIL’s lack of any EU turnover or sales
    - The FTC obtains dismissal of its Section 13(b) complaint on the grounds it is no longer necessary given the pendency of the EC’s suspense period (June 1, 2021)
  - EC opens formal Phase II investigation (July 22, 2021)
  - EC formally prohibits Illumina’s acquisition of GRAIL (September 6, 2022)

Antitrust timeline

- Reacquisition closes
  - Illumina closes the acquisition of GRAIL with no advance public notice despite ongoing FTC litigation and EC (on or about August 18, 2021)
    - Company publicly commits to hold GRAIL as a separately managed subsidiary under interim measures per EC and FTC expectations, pending litigation
  - The FTC does not refile for any preliminary injunctive relief in federal court and continues its administrative litigation
- EC “gun jumping” investigation
  - EC opens a “gun jumping” investigation into whether Illumina violated the standstill rule under EU Merger Regulation by closing prior to clearance (October 29, 2021)
    - The EC imposes unprecedented interim “hold-separate” measures requiring Illumina to keep GRAIL operationally and competitively independent, overseen by an independent “Hold Separate Manager” (October 21, 2021)
  - The EC imposes a record €432 million “gun-jumping” fine on Illumina for closing before approval, the largest ever for a breach of the EUMR, and a nominal €1,000 fine on GRAIL
  - Illumina and GRAIL challenged the European Commission’s assertion of jurisdiction under Article 22 by filing an application for annulment before the EU General Court (April 28, 2021)
  - On July 13, 2022, the EU General Court upheld the EC’s decision, confirming its authority to review the transaction despite no EU turnover for GRAIL
  - Illumina and GRAIL appealed the General Court’s decision to the Court of Justice of the European Union (September 23, 2022)

Antitrust timeline

- FTC litigation
  - ALJ dismisses complaint on the merits (September 1, 2022)
    - Notes the lack of imminent commercial rivals and insufficient evidence that Grail's competitors faced a significant foreclosure threat
    - Finds that Complaint Counsel had failed to prove its prima facie case that the merger created a substantial risk of harm to competition
  - Full Commission reverses and orders divestiture (April 3, 2023)
    - Reviews de novo
    - Finds the acquisition would likely substantially lessen competition in the U.S. market for multi-cancer early detection (MCED) tests
    - Orders Illumina to divest GRAIL
  - Fifth Circuit vacates and remands (December 15, 2023)
    - Finds that the FTC made out its prima facie case
    - But finds that FTC applied the wrong legal standard for assessing the "fix"
- Subsequent developments
  - Illumina announces that it will divest GRAIL and not pursue further appeals (December 17, 2023)
  - In the first half of 2024, Illumina prepares its divestiture plan, culminating with the spin-off of GRAIL as an independent public company trading under the symbol GRAL on Nasdaq (June 24, 2024)
    - Illumina retains approximately 14.5% of GRAIL's outstanding shares after the divestiture
  - After completion of the divestiture, the FTC dismisses its administrative complaint against Illumina (August 2024)
  - The EU Court of Justice annuls the EC's original jurisdictional decision and all resulting enforcement actions (including the prohibition, fine, and divestiture order), but by then GRAIL had been divested and Illumina had complied with regulatory orders (September 3, 2024)

The FTC's administrative complaint

- Gravamen
  - Alleged the transaction would substantially lessen competition in the U.S. market for multi-cancer early detection (MCED) tests by raising the risk of harm to innovation, price, quality, and consumer choice by foreclosing/RRC to Illumina's NGS platform to Grail's rivals
- Market definition
  - *Relevant product market*: Research, development, and commercialization of MCED tests that can detect multiple types of cancer in asymptomatic people, using blood-based ("liquid biopsy") technology
  - *Relevant geographic market*: United States
    - Need for FDA approval
  - NB: No existing commercial MCED tests
    - But multiple firms were in advanced development
    - GRAIL's Galleri was earliest to market

The FTC's administrative complaint

- Ability to foreclose/RCC Illumina's NGS platforms
  - Illumina described as the dominant (and only viable) U.S. supplier of next-generation sequencing (NGS) platforms—an essential input for MCED test developers
  - Virtually all current and potential MCED tests depend on Illumina's NGS systems, with no timely or likely alternative entry by rivals
- Incentive to foreclose/RCC Illumina's NGS platforms
  - Without the merger, Illumina benefits from maximizing profits from NGS products across all test developers
  - After the merger, Illumina's incentive shifts to maximizing profits of the combined firm, which creates an incentive to raise costs to Grail's rivals to impede MCED development and shift sales to GRAIL even if Illumina loses some NGS revenue
- Anticompetitive effect
  - RRC likely to reduce rivals' ability to compete, impeding innovation and consumer access to improved MCED testing
- Remedy
  - Divestiture of GRAIL

Illumina's "Open Offer"

- Idea
  - To deal with the FTC's foreclosure concerns, Illumina advanced the "Open Offer" to ensure that Illumina would treat GRAIL's rivals nondiscriminately with GRAIL
  - Formally submitted to the FTC on February 12, 2021
  - Updated and discussed terms with the Commissioners throughout March 2021
  - Released the finalized Open Offer publicly on March 30, 2021—the same day the FTC's complaint was filed
- Legal structure
  - Structured as an irrevocable, binding contractual offer governed by New York law
  - If accepted by a qualifying oncology customer, would create a standardized enforceable supply agreement between Illumina and the customer, independent of FTC or court consent, with contractual remedies available for breach
    - Available to all for-profit U.S. oncology customers developing MCED or other cancer tests
    - Effective for 12 years (through August 18, 2033), and can be accepted any time until August 18, 2027

Illumina's "Open Offer"

- Commitments
  - Nondiscrimination guarantee
    - Same or better pricing, service, and product access as provided to GRAIL—including new and pre-release sequencing products, technical support, and future innovations.
  - Most-favored-nation protections
    - Customers receive the benefit of any lower price or better term offered to GRAIL or to any other equivalent customer.
  - Product continuity commitments
    - No discontinuation of supplied products so long as customer continues to purchase
    - Continued supply for development and IVD applications
  - Confidentiality and firewalls enforced
    - Customer information must be kept strictly separate from GRAIL
    - Periodic audits by independent firms and mandatory disclosure of any breaches.
  - Dispute resolution
    - Customers may invoke binding arbitration, with enforceable remedies including injunctive relief and restoration of the status quo
  - Transparent public posting
    - Pricing, product, and compliance data regularly posted and independently monitored

Illumina's "Open Offer"

- Industry reception
  - A majority of MCED developers accepted the Open Offer or equivalent agreements in the course of the litigation
  - Some rivals, however, criticized behavioral commitments as inferior to structural relief and raised questions about monitoring and evasion risks
- FTC response
  - Rejected the Open Offer as insufficient behavioral relief because it—
    - Would not prevent all possible ways Illumina could harm GRAIL's rivals
    - Had gaps and flaws in enforceability and monitoring
    - Was subject to potential unilateral amendments, loopholes, renegotiation, and that legal dispute resolution could delay effective relief in critical moments
  - Concluded that only a structural remedy (divestiture) could negate its concerns

The ALJ's decision: Core findings

- Outcome
  - Complaint dismissed for failure to make out a prima facie case (Sept. 1, 2022).
- Critical question for input foreclosure
  - Would the merger give the merged firm the ability and profit-maximizing incentive to foreclose/RRC to NGS technology to GRAIL's MCED rivals
- Legal tests
  - "Ability and incentive"
  - The Brown Shoe vertical factors
    - ALJ said that Complaint Counsel used these factors to "bolster" its prima case
    - ALJ appears not to regard the Brown Shoe factors as an independent basis for establishing Section 7 harm in a vertical foreclosure case

The ALJ's decision: Relevant market

- Affected market (confused)
  - Found that FTC's alleged market of "research, development, and commercial development" of MCED tests was not useful in assessing the central question
    - Would have included all firms active in doing MCED R&D
    - Impossible to assess competitive harm because all third-party firms were not close to FDA approval and commercialization
    - ALJ found the relevant market should focus on actual and imminent MCED test availability, not on R&D alone
  - MCED tests (including near-future entrants)
    - GRAIL the only actual market participant

The ALJ's decision: "Ability and incentive"

- Ability to foreclose/RRC
  - MCED tests require NGS consoles and supplies
  - Illumina is the only NGS supplier
  - ∴ Merged firm has the ability to foreclose/RCC
- Incentive to foreclose
  1. FTC failed to show new firms would enter the MCED market in the near-future
     - FDA testing and authorization made likely new entry at least five to seven years out
     - Too distant to assess any foreclosure/RRC incentive
  2. FTC failed to show that significant rivals to GRAIL in MCED tests would emerge
     - Illumina's profit-maximizing incentive is to—
       - Promote new entry of firms that do not compete closely with GRAIL (low diversion ratios) to maximize demand for NGS consoles and supplies
       - Only impede entry or success of firms that compete closely and significantly with GRAIL (high diversion ratios)
  3. FTC failed to show that Open Offer would be ineffective in preventing foreclosure/RRC to new close rivals if they did emerge
     - NB: The ALJ placed the burden of a prima facie showing that the "fix" did not work in Step 1 of *Baker Hughes*

The ALJ's decision: *Brown Shoe* factors

- The *Brown Shoe* factors
  - In addition to the "ability and incentive" test, the FTC also used the *Brown Shoe* vertical test "bolster" its prima facie case
  - The *Brown Shoe* vertical factors are indicia that the Supreme Court recognized as circumstantially probative of a vertical anticompetitive effect, including—
    1. The share of the foreclosed market
    2. The nature and purpose of the transaction
    3. The trend toward vertical integration
    4. The likelihood of foreclosure of market access
    5. The structure and characteristics of the market
    6. Historical experience of similar vertical transactions
    7. The impact on potential competition

    NB: As with the *Brown Shoe* "practical indicia" for market definition, these factors are illustrative, not exhaustive
  - At the administrative hearing, the FTC Complaint Counsel focused on four factors—
    1. The nature and purpose of the transaction
    2. The likelihood of foreclosure
    3. The degree of merged firm's market power
    4. Barriers to entry

Applied to the FTC's alleged relevant market of "research, development, and commercial development" of MCED tests

The ALJ's decision: *Brown Shoe* factors

- The *Brown Shoe* factors (cont.)
  - ALJ: *Brown Shoe* factors insufficient to make out prima facie case
    1. No imminent competitors to foreclose
    2. FTC's market definition problems undermined the *Brown Shoe* factor analysis
    3. Open Offer undermined foreclosure likelihood

Bottom line: The FTC failed to make out a prima facie case that it was profit-maximizing for Illumina to foreclose GRAIL's rivals from its NGS consoles and supplies and sacrifice upstream platform profits in order to increase its downstream profits

Appeal to the Commission: Core findings

- Outcome
  - Commission reversed ALJ's initial decision (April 3, 2023)
  - Unanimous 4-0 vote finding the acquisition violated Section 7 of the Clayton Act
  - Ordered Illumina to divest GRAIL within 180 days
- Standard of review
  - Commission reviewed de novo
  - Not bound by ALJ's credibility determinations or factual findings
  - Applied its own independent judgment to evidence
- Critical question for input foreclosure (full Commission version)

  Would the merger give Illumina the ability or incentive to foreclose/RRC NGS technology to GRAIL's MCED rivals?

  - Key difference form ALJ:
    - The Commission used an "ability OR incentive" disjunctive test
    - The ALJ used an "ability AND incentive" conjunctive test

  The Commission was trying to make new law

The Commission: Market Definition

- Product market
  - "Research, development, and commercialization of MCED tests" in the United States
  - Commission accepted the FTC's proposed market definition
  - Rejected ALJ's concerns about including firms in R&D stage
  - Found the market properly captured innovation competition
- Geographic market
  - United States (same as ALJ)
- Commission's reasoning
  - MCED tests have peculiar characteristics and uses distinct from other cancer tests
  - MCED developers view themselves as competing in distinct market
  - Industry recognition, specialized customers, distinct pricing support market
  - Innovation race to commercialize MCED tests is the competitive dynamic

The Commission: Ability to Foreclose

- Illumina's monopoly position
  - Illumina is the sole supplier of NGS platforms and consumables
  - All MCED test developers depend on Illumina's NGS technology
  - No current or near-term alternatives to Illumina's NGS platforms
- Mechanisms of foreclosure
  - Raise prices to rivals
  - Degrade service, support, or access to new technology
  - Delay or deny access to critical inputs
  - Provide preferential treatment to GRAIL
  - Share rivals' confidential information with GRAIL
- Commission found ability was clear and undisputed
  - Illumina conceded it had technical ability to foreclose

Under the Commission's legal test, once ability to foreclose has been found, incentive to foreclose was irrelevant

The Commission: Incentive to foreclose

- Commission rejected ALJ's incentive analysis
  - Found record showed foreclosure would be profit-maximizing
  - Even small downstream gains could justify upstream sacrifice
- Key evidence Commission credited
  - Illumina's own documents showing GRAIL acquisition motivated by competitive concerns
  - GRAIL's Galleri test already commercially launched (not speculative)
  - Evidence of rivals' dependence on Illumina and vulnerability to foreclosure
  - Industry testimony about importance of Illumina relationship
- Diversion ratio analysis
  - Customers of MCED rivals (once commercialized) would divert significant sales to GRAIL if foreclosed—Even partial foreclosure (raising rivals' costs) would benefit GRAIL
  - Foreclosure need not be complete to be profitable to merged firm
- Commission's conclusion
  - Foreclosure would allow GRAIL to maintain/extend its head start
  - Reduced innovation and higher prices in MCED market
  - Harm to competition outweighed any platform revenue loss

The Commission: *Brown Shoe* factors

- Considered *Brown Shoe* as an independent test of vertical harm
  - NB: This is a departure from the ALJ's decision, which viewed *Brown Shoe* as merely "bolstering" the ability/incentive test, not as an independent basis for establishing vertical foreclosure harm
- Found four *Brown Shoe* factors independently established a prima facie case
  - *Nature and purpose*: Illumina reacquired GRAIL to control MCED market
  - *Likelihood of foreclosure*: High, given Illumina's monopoly and rivals' dependence
  - *Merged firm's market power*: Illumina has 100% market share in NGS platforms (the input being foreclosed)
  - *Barriers to entry*: Extremely high for NGS platform market; significant for MCED test market
- Rejected ALJ's *Brown Shoe* analysis
  - Disagreed that lack of imminent competitors undermined *Brown Shoe* analysis
  - Emphasized potential and nascent competition counts under Section 7
  - Found factors supported foreclosure concern even for potential/future competition

The Commission: The Open Offer

- Commission found Open Offer inadequate to rebut prima facie case
  - Open Offer does not eliminate Illumina's ability or incentive to foreclose
  - Multiple mechanisms of foreclosure not addressed by Open Offer
- Specific inadequacies identified:
  - Does not cover service quality, support, or access to innovation
  - Does not prevent preferential treatment of GRAIL or information sharing to GRAIL
  - Limited enforcement mechanisms; difficult to detect violations
  - Does not address strategic timing of new product releases
  - Expires before MCED market fully develops
- Standard for evaluating remedies
  - Burden on respondents to prove remedy eliminates competitive concern
  - Commission found Illumina failed to meet this burden
  - Remedy must be clear, enforceable, and comprehensive
- Commission's holding
  - Open Offer is a "fix" that does not adequately address foreclosure risk
  - Even if burden placed on government (as ALJ did), evidence supports inadequacy

The Commission: Bottom Line

- Prima facie case established
  - FTC proved merger likely to substantially lessen competition under both:
    - Ability or incentive test ✓
    - *Brown Shoe* factors ✓
- Rebuttal failed
  - Illumina's efficiencies insufficient and not merger-specific
  - Open Offer does not eliminate competitive harm
  - No cognizable defense established
- Remedy ordered
  - Full divestiture of GRAIL within 180 days
  - Monitored compliance to ensure complete separation
- Bottom line:

  The Commission found the FTC proved a prima facie case that the merger would give Illumina the ability or incentive to foreclose GRAIL's rivals from NGS technology, harming innovation competition in the MCED test market, and that Illumina's Open Offer was insufficient to rebut this showing.

Appeal to the Fifth Circuit

- Outcome
  - Affirmed the FTC established a prima facie Section 7 violation (December 15, 2023)
  - Found the FTC applied the wrong legal standard in assessing Illumina's Open Offer
  - Vacated divestiture order and remanded for reconsideration of Open Offer under correct legal standard—Did not decide ultimate liability
- Standard of review
  - Court reviews the Commission's decision, not the ALJ's
  - Legal questions reviewed de novo
  - Factual findings reviewed for substantial evidence
    - → Bound by Commission's factual determinations if supported by evidence "a reasonable mind might accept as adequate"
- Key holdings
  - The Commission properly defined relevant market
  - Substantial evidence supported the Commission's prima facie case under *both* ability/incentive test and *Brown Shoe* factors (regarded as independent tests)
  - Commission applied wrong legal standard in evaluating the Open Offer in *BH* Step 2 & 3
  - Commission properly rejected Illumina's claimed efficiencies

The Fifth Circuit: Relevant Market

- Upheld Commission's market definition
  - Relevant market: "Research, development, and commercialization of MCED tests" in the United States
  - Rejected Illumina's argument that market should be limited to currently commercialized tests
- Reasoning on research and development markets
  - Products need not be identical to be in same market—only "similar in character or use"
  - Requiring hard metrics for substitutability where only one product had been commercialized would prevent R&D markets from ever being recognized
  - Would contravene Section 7's purpose "to arrest anticompetitive tendencies in their incipiency"
- Evidence supporting market definition
  - Grail's own internal documents showed it viewed itself in active competition with other MCED developers
  - Competing MCED tests (especially CancerSEEK) have been clinically validated
  - Other developers have concrete plans for FDA approval trials
  - *Brown Shoe* practical indicia supported market boundaries

The Fifth Circuit: Ability/incentive test

- Legal test
  - Requires both ability *and* incentive
- Ability to foreclose
  - Illumina is monopoly supplier of NGS platforms—no alternatives exist
  - Illumina conceded it had ability to foreclose postmerger
  - Court rejected Illumina's argument that merger must *increase* the ability to foreclose
- Incentive to foreclose analysis
  - Merger increases Illumina's ownership stake in GRAIL from 12% to 100%
  - The merger significantly increases the amount Illumina would earn from sale of the Grail test than from rival's test → increases Illumina's incentives to impede MCED rivals
- Court rejected Illumina's diversion argument
  - Illumina claimed no current sales to divert because Galleri is only test on market
  - Relevant market includes tests in development
  - When rival tests reach market, they will divert sales from Grail (or vice versa w/ foreclosure)
- Court rejected Illumina's reputational harm argument
  - Illumina could engage in subtle foreclosure without triggering suspicion

The Fifth Circuit: The *Brown Shoe* factors

- Substantial evidence supported prima facie case under *Brown Shoe*
  - Commission analyzed four key factors (not all seven required)
  - “No precise formula" for applying *Brown Shoe* factors
  - *Brown Shoe* Court has found vertical merger unlawful examining only three factors
- Four factors supported Commission
  - *Likelihood of foreclosure*: High, since Illumina sole supplier → ability to foreclose rivals
  - *Nature and purpose*: Acquisition of downstream customer by sole-source supplier; transforms Illumina's business model to compete in downstream market
  - *Degree of market power*: Merger would lead to MCED market power in merged firm (long-term impact)
  - *Barriers to entry*: Rival firms disincentivized from investing in MCED development postmerger
- Rejected Illumina’s arguments
  - Disagreed that Commission should look only at immediate effect (Galleri being only current test)
  - Commission properly considered merger’s long-term impact
  - Commission gave appropriate weight to testimony from rival developers

The Fifth Circuit: The Open Offer—Burdens

- Court rejected both parties' positions on allocation of burden of proof
  - *Illumina's position*: Open Offer must be part of prima facie case ❌
  - *Commission's position*: Open Offer only evaluated at remedy stage ❌
  - *Court's holding*: Open Offer evaluated at rebuttal stage✓
    - Merging parties have burden of production in *Baker Hughes* Step 2 to adduce evidence on—
      - The terms of the Open Offer, *and*
      - The effectiveness of the Open Offer in ensuring that the restructured transaction will not result in a substantial lessening of competition
    - FTC has burden of persuasion under *Baker Hughes* Step 3 to show that the restructured transaction, with the Open Offer in place, is nonetheless likely to substantially lessen competition
- Court's reasoning
  - Open Offer is "somewhere between a fact and a remedy"
  - Postsigning, preclosing adjustment to status quo
  - Implemented to stave off concerns about anticompetitive conduct
  - Became effective before evidentiary hearing began
    - Not conditioned upon being needed as a remedy to a finding of liability

The Fifth Circuit: The Open Offer–Legal Error

- Commission applied wrong legal standard
  - Commission required Illumina to show Open Offer would "eliminate" all anticompetitive effects resulting from the transaction (total negation standard)
  - Commission mistakenly treated Open Offer as a "remedy"
- Correct standard under Section 7
  - Illumina only had the burden of persuasion required to show Open Offer sufficiently mitigated effects so that the restructured transaction was no "likely to substantially lessen competition"
  - Total negation standard would "effectively erase the word substantially from Section 7"
- Fifth Circuit's holding
  - Commission's standard incompatible with plain language of Clayton Act
  - Vacated Commission's order and remanded for reconsideration under proper standard

The Fifth Circuit: Efficiencies

- Upheld Commission's rejection of efficiencies
  - "To be cognizable as rebuttal evidence, an efficiency must be (1) merger specific, (2) verifiable in its existence and magnitude, and (3) likely to be passed through, at least in part, to consumers."
  - Commission found none of Illumina's claimed efficiencies met these requirements
- Substantial evidence supported Commission's rejection
  - *Royalty elimination*: Not likely to be passed through to consumers ✓
  - *Double marginalization*: Not verifiable—no model for calculating benefit ✓
  - *Supply chain/operational efficiencies*: Not verifiable—no underlying model, only dollar assertion ✓
  - *R&D efficiencies*: Not verifiable—relied only on executive testimony, no quantification ✓
  - *FDA/payer approval acceleration*: Not cognizable—did not establish it would occur or how achieved ✓
- Observation
  - The Fifth Circuit did not address the allocation of the burdens of proof in an efficiencies defense
  - Just found substantial evidence supported the Commission's determinations

The Fifth Circuit: Bottom Line

- What the Fifth Circuit affirmed
  - Commission's market definition: Research, development, commercialization of MCED tests
  - Substantial evidence supported prima facie case under ability and incentive test
  - Substantial evidence supported prima facie case under *Brown Shoe* factors
  - Commission properly rejected Illumina's claimed efficiencies
  - [All constitutional challenges fail]
- What the Fifth Circuit vacated
  - Commission's Open Offer analysis used wrong legal standard (total negation)
  - Vacated the judgment finding a Section 7 violation
- Remand instructions
  - Commission must reconsider Open Offer under proper standard at the rebuttal stage
    - Illumina had the burden of production to show—
      - The terms of the Open Offer, *and*
      - The effectiveness of the Open Offer in ensuring that the restructured transaction will not result in a substantial lessening of competition
    - The Commission had the burden of persuasion to show that the restructured transaction, with the Open Offer in place, is nonetheless likely to substantially lessen competition

The Fifth Circuit: Bottom Line

- Bottom line:
  - The Fifth Circuit largely validated the Commission's aggressive approach to vertical mergers, including—
    - Use of R&D markets
    - *Brown Shoe* vertical factors
    - Protection of nascent competition
  - But required the Commission to apply Section 7's actual standard ("substantially lessen") rather than a total negation standard when evaluating remedies at the rebuttal stage
- *Query*: How much of the Fifth Circuit's decision is likely to "stick"?