

**UNITED STATES OF AMERICA  
BEFORE THE FEDERAL TRADE COMMISSION  
OFFICE OF ADMINISTRATIVE LAW JUDGES**

**In the Matter of**

**Illumina, Inc.,  
a corporation,**

**and**

**GRAIL, Inc.,  
a corporation.**

**DOCKET NO. 9401**

**COMPLAINT COUNSEL'S POST-TRIAL  
PROPOSED FINDINGS OF FACT AND CONCLUSIONS OF LAW**

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**TABLE OF CONTENTS**

**I. BACKGROUND** ..... 1

**A. ILLUMINA** ..... 1

        1. Illumina Is a Dominant Provider of Next Generation Sequencing Platforms ..... 1

        2. Formation of Grail ..... 2

        3. Spinoff of Grail (Reducing Ownership to Less Than 50 Percent) ..... 5

**B. GRAIL** ..... 8

        1. Grail’s Galleri MGED Test ..... 8

        2. [REDACTED] ..... 17

        3. Grail’s Intellectual Property Holdings ..... 18

        4. Grail Prepared to Go Public Prior to Acquisition ..... 19

**C. THE TRANSACTION** ..... 22

        1. [REDACTED] ..... 23

        2. [REDACTED] ..... 24

        3. The Parties Closed the Transaction Despite the Possibilities of Fines, Reputation Consequences, and Other Government Enforcement Action ..... 24

**II. INDUSTRY BACKGROUND** ..... 26

**A. CANCER IS THE SECOND LEADING CAUSE OF DEATH IN THE UNITED STATES** ..... 26

**B. CURRENT CANCER SCREENING METHODS** ..... 26

        1. Cancer Screening Methods Currently Exist for Only a Handful of Cancer Types ..... 26

        2. Most Cancers Detected at Late Stages, Leading to Poor Outcomes ..... 28

**C. MGED TESTS ARE POISED TO REVOLUTIONIZE HOW CANCER IS DETECTED AND TREATED** ..... 30

        1. The Advantages of Liquid Biopsy ..... 30

        2. Analyte Molecules Present in Blood and Other Body Fluids ..... 32

        3. Classes of Biomarkers Utilized for Cancer Detection ..... 34

        4. MGED Tests Rely on Illumina NGS to Simultaneously Examine Thousands of Cancer Biomarkers in cfDNA ..... 38


        5. Illumina and Grail Were Not the First to Discover the Use of cfDNA for Cancer Screening Technology ..... 39

        6. MGED Test Background ..... 41

**D. THE U.S. MGED TEST MARKET IS EXPECTED TO REACH TENS OF BILLIONS OF DOLLARS ANNUALLY IN REVENUES** ..... 52

1.	Illumina Expects Cancer Screening to Be “Probably the Single Biggest Market Segment That We Can Imagine” .....	52
2.	Other MCED Developers Also Project Tens of Billions of Dollars in Revenues for the MCED Test Market.....	54
E.	REGULATORY APPROVAL PROCESS AND REIMBURSEMENT FRAMEWORK FOR MCED TESTS.....	55
1.	Laboratory Developed Tests (LDTs).....	55
2.	FDA Approval Process .....	56
3.	Payer Reimbursement .....	61
<b>III.</b>	<b>THE RELEVANT PRODUCT MARKET IS THE MARKET FOR THE RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION OF MCED TESTS.....</b>	<b>66</b>
A.	BLOOD-BASED CANCER DETECTION TESTS DESIGNED FOR PURPOSES OTHER THAN CANCER SCREENING ARE NOT SUBSTITUTES FOR MCEDS .....	67
1.	Other Blood-Based Cancer Detection Tests Serve a Different Function.....	67
B.	OTHER CANCER SCREENING TESTS ARE NOT SUBSTITUTES FOR MCED TESTS .....	70
1.	USPSTF Cancer Screening Methods Are Complementary to MCED Tests .....	70
2.	Other Non-USPSTF Single-Cancer Blood-Based Tests Are Not Close Substitutes for MCED Tests .....	73
C.	BROWN SHOE FACTORS SHOW THAT THE RELEVANT PRODUCT MARKET IS MCED TESTS.....	77
1.	MCED Tests Will Have Distinct Pricing and Reimbursement from Other Oncology Tests.....	77
2.	MCED Tests Target Distinct Customers from Other Oncology Tests .....	80
3.	Both Blood-Based and Non-Blood Based Single-Cancer Screening Tests Have Different Customers.....	81
4.	DAC, Therapy Selection, and MRD Have Different Customers .....	82
5.	The Parties Recognize That MCED Testing Is Its Own Relevant Market.....	83
6.	Industry Participants View MCED Tests as Its Own Relevant Market.....	88
7.	Legislators, Regulators, and Others Discuss an MCED Market.....	91
D.	THE HYPOTHETICAL MONOPOLIST TESTS SHOWS MCED TESTS ARE A RELEVANT PRODUCT MARKET .....	93
<b>IV.</b>	<b>THE UNITED STATES IS THE RELEVANT GEOGRAPHIC MARKET.....</b>	<b>94</b>
A.	THE UNITED STATES HAS UNIQUE REGULATORY REQUIREMENTS FOR MCED TESTS.....	94

1.	Centers for Medicare & Medicaid Services Oversees Laboratory Developed Tests .....	95
2.	The FDA Will Classify MCED Tests as Class III Medical Devices Requiring Pre-Market Approval .....	96
B.	COMMERCIALIZATION OF AN MCED TEST IN THE UNITED STATES WILL REQUIRE FDA APPROVAL BECAUSE OF U.S. PAYER REQUIREMENTS.....	97
1.	CMS Will Not Reimburse for an MCED Test Without FDA Approval .....	97
2.	FDA Approval Is Also Important to Obtaining Broad Commercial Reimbursement in the United States.....	98
3.	Obtaining FDA Approval and U.S. Payer Coverage Is Critical for Commercial Adoption of MCEds in the United States .....	99
C.	RESPONDENTS RECOGNIZE THE UNITED STATES AS A DISTINCT MARKET .....	99
V.	<b>ILLUMINA NGS IS A NECESSARY INPUT TO MCED TESTS.....</b>	<b>100</b>
A.	NEXT GENERATION SEQUENCING OVERVIEW .....	100
1.	Next Generation Sequencing Determines the Order of Nucleotides in DNA Molecules .....	100
2.	Short-Read Versus Long-Read Sequencing.....	101
B.	MCED PRESENTS ENORMOUS SCIENTIFIC AND TECHNICAL CHALLENGES .....	104
C.	MCED TESTS REQUIRE HIGH-THROUGHPUT, HIGHLY ACCURATE, LOW-COST NGS PLATFORMS .....	105
1.	MCED Tests Need High-Throughput NGS Machines to Sample an Extremely High Number of cfDNA Fragments from Each Blood Sample .....	106
2.	MCED Tests Need NGS with High Accuracy and Low Error Rates to Correctly Identify ctDNA and Increase Sensitivity and Specificity .....	109
3.	MCED Tests Need Low-Cost Sequencing to Screen the General Population.....	111
4.	An MCED Developer Planning to Sell a Kitted MCED Test Requires an FDA-Cleared NGS Platform.....	114
D.	ONLY ILLUMINA NGS PLATFORMS MEET THE REQUIREMENTS OF MCED TESTS .....	115
1.	Illumina’s Industry Leading NGS Technology.....	116
2.	MCED Test Developers Testified That They Need and Rely on Illumina NGS as Their Only NGS Option .....	120
3.	Illumina Understands That Its NGS Platforms Far Surpass Other Platforms on High Throughput, High Accuracy, and Low Cost.....	133
4.	Other Industry Participants Recognize that Illumina NGS Platforms Are the Only Viable Option for MCED Testing .....	135

E.	NON-ILLUMINA NGS PLATFORMS DO NOT MEET THE REQUIREMENTS OF MCED TESTS.....	135
1.	Thermo Fisher Is Not an Option for MCED Test Developers .....	135
2.	BGI Is Not an Option for MCED Test Developers.....	142
3.	“Extremely Inefficient” Long-Read NGS Is Not an Option for MCED .....	150
F.	OTHER TESTING TECHNOLOGIES ARE NOT VIABLE SUBSTITUTES FOR NGS FOR MCED TESTS.....	157
1.	Microarray Platforms .....	158
2.	PCR-Based Technology.....	162
3.	Other (Sanger & Proteomics).....	169
G.	SUFFICIENT AND TIMELY ENTRY OF A NEW SHORT-READ NGS PLATFORM SUITABLE FOR MCED TEST DEVELOPERS IS UNLIKELY.....	170
1.	Significant Scientific, Legal, and Commercial Barriers to Entry Exist .....	170
2.	Even if a Company Develops a New NGS Platform, Significant Barriers to Commercialization Exist and It Will Take Years for a New Entrant to Gain the Reputation and Enough Widespread Commercial Use to Be an Option for MCEDs .....	173
3.	No NGS Platform Likely to Enter the NGS Market That Would Be a Viable Option for MCED Test Developers in a Timely Manner.....	179
4.	Even if Another NGS Platform Entered the U.S. Market Comparable to Illumina’s Current Platform, Illumina Plans to Continue to Improve its Existing Platform.....	194
H.	SWITCHING TO ANOTHER NGS PLATFORM WOULD CAUSE SIGNIFICANT DELAYS, REQUIRE SIGNIFICANT COSTS, AND POSE REGULATORY AND FINANCIAL RISKS FOR MCED TEST DEVELOPERS.....	199
1.	MCED Tests are Developed to Run on a Specific NGS Platform.....	199
2.	 .....	200
3.	Illumina, Grail, and Other NGS Market Participants Recognize High Switching Costs.....	208
4.	Switching NGS Platforms Is Even More Difficult if the MCED Test Has Begun the FDA Approval Process .....	212
<b>VI.</b>	<b>COMPETITORS ARE RACING TO DEVELOP MCED TESTS .....</b>	<b>216</b>
A.	EXACT SCIENCES IS DEVELOPING AN MCED TEST CALLED CANCERSEEK.....	216

- 1. Exact Is a Commercial Oncology Company That Launched Cologuard, an FDA-Approved and CMS-Reimbursed Stool-Based Colorectal Cancer Screening Test .....216
- 2. In January 2021, Exact Acquired Thrive, the Developer of an MCED Test Called CancerSEEK.....218
- 3. CancerSEEK is an MCED Test Designed to Detect All Cancer Types Using Multiple Analytes and Next Generation Sequencing .....220
- 4. [REDACTED] .....228
- 5. CancerSEEK Has Already Undergone a Prospective, Interventional Clinical Trial, and Exact is Preparing for Its FDA Registrational Trial .....228
- 6. [REDACTED] .....236
- 7. Prior to Acquiring Thrive and CancerSEEK, Exact Conducted MCED Research & Development, Dating Back to 2009 .....237
- 8. Background on Exact Sciences’ Oncology Start-Up Pedigree: Product Development, Regulatory Success, and Salesforce Expansion .....239
- 9. Exact and Grail Consider One Another Competitors in MCED .....243

B. [REDACTED]

- C. GUARDANT HEALTH IS DEVELOPING AN MCED TEST CALLED LUNAR-2 .....250
  - 1. Guardant Is An Established Oncology Test Developer .....250
  - 2. Guardant Is Developing an MCED Test Called LUNAR-2 .....251

3. [REDACTED] .....255

4. Guardant Is Committed to Improving Its MCED Test Over Time .....256

5. [REDACTED] .....257

6. [REDACTED] .....258

7. Guardant and Grail Consider One Another Competitors in MCED .....259

D. FREENOME IS DEVELOPING AN MCED TEST AS AN EXPANSION OF ITS COLORECTAL CANCER SCREENING TEST .....259

1. Background .....259

2. Freenome's MCED Test Technological Platform Is Designed to Be Able to Host a Multi-Cancer Test .....259

3. [REDACTED] .....263

4. [REDACTED] .....264

5. [REDACTED] .....264

E. SINGLERA HAS ALREADY CONDUCTED A 100,000 SAMPLE TRIAL FOR ITS MCED TEST IN DEVELOPMENT—PANSEER .....264

1. Background .....264

2. Singlera's Single-Cancer Screening Tests .....265

3. Singlera is Developing an MCED Test—PanSeer .....266

4. Singlera's PanSeer Completed a 100,000 Sample Clinical Trial .....269

5. Singlera Has Invested Approximately \$250 Million on PanSeer's Development .....271

6. Singlera Expects to Launch PanSeer in the U.S. in 2028 and Will Not Offer PanSeer as an LDT in the U.S. ....271

7. Singlera and Grail Consider One Another Competitors in MCED .....271

F. HELIO HEALTH IS DEVELOPING ITS MCED TEST ON THE SAME PLATFORM AS ITS HELIO LIVER TEST .....271

1. Background .....271

2. HelioLiver Test .....272

3. Helio Is Developing an MCED Test on the HelioLiver Technological Platform .....273

4. [REDACTED] .....278

5. [REDACTED] .....278

6.	[REDACTED]	279
7.	Helio and Grail Consider One Another Competitors in MCED	279
G.	[REDACTED]	279
1.	[REDACTED]	279
2.	[REDACTED]	280
3.	[REDACTED]	281
4.	[REDACTED]	283
5.	[REDACTED]	283
H.	OTHER MCED TEST DEVELOPERS	283
1.	[REDACTED]	283
2.	[REDACTED]	284
3.	[REDACTED]	284

**VII. THE PROPOSED MERGER WILL SUBSTANTIALLY LESSEN COMPETITION IN THE U.S. MCED TEST MARKET**.....284

A.	ILLUMINA HAS THE ABILITY TO HARM GRAIL’S RIVALS	284
1.	ILLUMINA HAS THE ABILITY TO IDENTIFY AND DISCRIMINATE AGAINST MCED TEST DEVELOPERS POSING COMPETITIVE THREATS TO GRAIL’S GALLERI TEST AND THE TOOLS TO FORECLOSE OR REDUCE THE COMPETITIVENESS OF GRAIL’S RIVALS	285
a)	ILLUMINA DESIGNS AND OFFERS PRODUCTS TAILORED FOR CUSTOMERS TO USE IN CERTAIN APPLICATIONS, INCLUDING PROVIDING CUSTOM KITS NOT JUST FOR SPECIFIC APPLICATIONS BUT ALSO FOR SPECIFIC CUSTOMERS	285
2.	ILLUMINA HAS A MULTITUDE OF TOOLS TO FORECLOSE OR REDUCE THE COMPETITIVENESS OF GRAIL’S MCED TEST RIVALS	297
a)	ILLUMINA CAN INCREASE PRICES OF ITS INSTRUMENTS AND REAGENTS	298
b)	ILLUMINA CAN DELAY OR FORECLOSE MCED RIVALS’ ACCESS TO NEW NGS TECHNOLOGY AND FAVOR AND ADVANTAGE GRAIL TO THE EXCLUSION AND DISADVANTAGE OF GRAIL’S MCED RIVALS	309
c)	ILLUMINA CAN REDUCE THE QUALITY OF ITS SUPPLY, SUPPORT, AND SERVICE TO GRAIL’S RIVALS	315
d)	ILLUMINA CAN DENY ACCESS TO INFORMATION, AGREEMENTS, AND LICENSES NECESSARY FOR FDA APPROVAL AND COMMERCIALIZATION OF MCED TESTS	328
e)	ILLUMINA CAN ALTER ITS NGS PRODUCTS TO DISADVANTAGE GRAIL’S MCED RIVALS	334



f)	Illumina Can Share the Competitively Sensitive Information of MCED Test Developers with Grail.....	336
g)	Illumina Can Control IP Access and Sue for Application-Specific IP Infringement .....	341
B.	ILLUMINA HAS THE INCENTIVE TO LESSEN COMPETITION IN THE U.S. MCED TEST MARKET BY DISADVANTAGING GRAIL’S RIVALS .....	343
1.	A Combined ILMN-Grail Has the Incentive to Maximize Firmwide Profits .....	343
a)	Pre-Merger, ILMN Had the Incentive to Promote Innovation and Multiple MCED Tests .....	343
b)	Post-Merger, ILMN Has the Financial Incentive to Maximize the Combined Profits of ILMN and Grail.....	346
2.	Potential Profits of MCED Tests Far Outweigh Profits from NGS Sales .....	348
a)	Illumina’s Documents and Market Participants Project Massive Revenue and Profit from the MCED Testing Market.....	348
b)	Market Participants Estimate That the MCED Market Will Grow to Be Significant .....	355
c)	Third Parties Foresee Illumina’s Changed Incentive as a Result of the Acquisition of Grail .....	355
d)	Dr. Scott Morton’s Analysis of Illumina’s Pre- and Post-Merger Profits Demonstrates Quantitatively Illumina’s Incentive to Foreclose and Raise Costs to GRAIL’s Rivals .....	358
3.	Other MCED Tests Are Likely to Compete Closely with Galleri .....	361
a)	Other MCED Developers Are Targeting the Same MCED Space .....	361
b)	[REDACTED] .....	387
c)	[REDACTED] .....	399
d)	[REDACTED] .....	400
e)	[REDACTED] .....	403
f)	Expert Analysis Confirms That the Acquisition Gives Illumina the Incentive and Ability to Disadvantage MCED Test Developers That Compete with Grail .....	404
4.	Patients Will Use a Single MCED Test for Screening .....	406
5.	MCEDs Will Compete on Various Product Features .....	406

- a) The Number of Cancers an MCED Test Screens for is One of Many Factors on which Tests Will Compete.....409
      - b) The Ability to Identify Tissue of Origin is One of Many Factors on Which Tests Will Compete .....410
- C. HARM TO GRAIL’S RIVALS WILL LEAD TO DECREASED INNOVATION IN THE U.S. MCED TEST MARKET .....413
  - 1. Entry to Participate in the MCED Race Requires Investment in R&D, with Fixed Investments—R&D and Clinical—to Launch an MCED Test.....414
    - a) The Transaction Will Give Illumina the Ability and Incentive to Raise Rivals Costs, Which Will Lower or Eliminate the Incentive for Grail’s Rivals to Invest in R&D Related to MCED Tests and Slow Innovation.....416
  - 2. MCED Developers Are Currently Competing—and Expect to Continue to Compete—on the Basis of Innovation, Not Just Price.....422
    - a) Despite Grail’s First-Mover Advantage, Other MCED Developers Will Have the Incentive to “Leapfrog” Grail by Offering Better Technology .....423
- D. ILLUMINA’S ANALYSIS AND BEHAVIOR IN OTHER MARKETS IN WHICH IT IS VERTICALLY INTEGRATED CORROBORATES EVIDENCE SHOWING ILLUMINA WILL HAVE THE ABILITY AND INCENTIVE TO DISADVANTAGE POTENTIAL COMPETITORS TO GRAIL.....426
  - 1. Illumina Identified Tools When It Launched and Spun Off Grail .....426
    - a) When Illumina Created a Grail as a Majority-Controlled Entity, Illumina Gave Grail Exclusive Discounts and Special Assistance .....426
    - b) After Illumina’s Sale of Its Majority Interest in Grail, Illumina “Leveled” the Playing Field Between Grail and Its Competitors .....431
    - c) After Illumina “Leveled the Playing Field,” Other Illumina Customers Successfully Developed Asymptomatic Cancer Tests .....436
  - 2. Illumina Identified and Used Similar Tools in the Oncology Therapy Selection Market.....437
    - a) Illumina Withheld Agreements to Prevent Competitors in the Therapy Selection Space from Cannibalizing Illumina’s Therapy Selection Product.....438
    - b) [REDACTED] }.....446

c) [REDACTED] .....474

3. Illumina Identified and Used Similar Tools in the NIPT Market.....491

    a) NIPT Overview .....491

    b) Illumina Acquired Verinata in 2013.....492

    c) NIPT Market Overview.....493

**VIII. RESPONDENTS’ BEAR THE BURDEN TO PROVE THAT COUNTERVAILING FACTORS ARE SUFFICIENT TO RESOLVE POTENTIAL HARMS: RESPONDENTS DO NOT MEET THIS BURDEN.....500**

A. ILLUMINA’S OPEN OFFER IS INSUFFICIENT TO RESOLVE POTENTIAL HARMS.....500

    1. A Structural Remedy is the Only Way to Adequately Protect Customers .....500

    2. Illumina Failed to Assuage Customers’ Concerns Regarding the Grail Acquisition.....504

    3. Illumina’s Open Offer Fails to Remedy Anticompetitive Harm from the Merger.....540

B. SUFFICIENT AND TIMELY ENTRY OF A NEW SHORT-READ NGS PLATFORM SUITABLE FOR MCED TEST DEVELOPERS IS UNLIKELY.....602

C. THE PARTIES’ CLAIMED EFFICIENCIES CANNOT JUSTIFY THE LIKELY HARM TO COMPETITION IN THE MCED MARKET .....602

    1. Acceleration of Galleri.....604

    2. Elimination of Double Marginalization.....668

    3. R&D Efficiencies.....673

    4. Elimination of Grail Royalty .....677

    5. Lab and Supply Chain Cost Savings.....679

    6. Other Claimed Efficiencies Are Neither Verifiable nor Merger Specific.....684

D. NON-MERGER ALTERNATIVES COULD REPLICATE ILLUMINA’S CLAIMED EFFICIENCIES .....685

    1. Grail Is Able to Raise Funds as an Independent Company .....685

    2. Grail’s Potential IPO Provided Access to Immediate Proceeds and Access to the Public Markets.....686

    3. Investors Remained Interested in a Grail IPO and Grail Remained Ready for an IPO After the Illumina Acquisition Was Announced.....697

    4. [REDACTED] .....697

**IX. APPENDIX A: WITNESS BACKGROUNDS.....698**

A. LAY WITNESSES WHO TESTIFIED AT TRIAL.....698

B. EXPERT WITNESSES WHO TESTIFIED IN TRIAL DEPOSITIONS .....715

C. SELECT WITNESSES WHO TESTIFIED BY DEPOSITION AND/OR INVESTIGATIONAL HEARING ONLY .....719

**X. APPENDIX B: GALLERI HAS NOT BEEN CLINICALLY SHOWN TO PROVIDE EARLY DETECTION OF MORE THAN 50 CANCERS IN AN ASYMPTOMATIC POPULATION.....726**

A. DEFINITIONS & BACKGROUND.....726

B. GRAIL’S CCGA STUDY DID NOT ASSESS GALLERI’S PERFORMANCE IN THE INTENDED USE POPULATION (ASYMPTOMATIC SCREENING POPULATION).....729

C. GRAIL’S CCGA STUDY DOES NOT REFLECT HOW GALLERI WOULD PERFORM IN THE INTENDED USE POPULATION (ASYMPTOMATIC SCREENING POPULATION).....732

D. GRAIL’S CCGA STUDY DOES NOT CONSTITUTE CLINICAL VALIDATION OF GALLERI AS A MULTI-CANCER EARLY DETECTION SCREENING TEST FOR AN ASYMPTOMATIC POPULATION .....734

E. GRAIL PUBLICLY CLAIMS ONLY THAT GALLERI CAN “DETECT A CANCER SIGNAL” FOR OVER FIFTY CANCER TYPES ON THE BASIS OF CCGA, NOT THAT GALLERI CAN “SCREEN” FOR FIFTY TYPES OF EARLY-STAGE CANCER .....735

F. GRAIL’S PATHFINDER STUDY PROVIDES CLINICAL EVIDENCE THAT GALLERI CAN IDENTIFY SEVEN TYPES OF EARLY-STAGE CANCER IN A SCREENING POPULATION.....737

G. GRAIL HAS NOT PRESENTED CLINICAL EVIDENCE THAT GALLERI CAN PROVIDE “EARLY DETECTION” OF MORE THAN 50 CANCER TYPES .....738

H. GRAIL HAS NOT PRESENTED CLINICAL EVIDENCE THAT GALLERI CAN PROVIDE “EARLY DETECTION” OF MORE THAN 50 CANCER TYPES, EVEN IN A NON-SCREENING SETTING .....738

I. GALLERI’S SENSITIVITY AT DETECTING STAGE I-III CANCERS FOR INDIVIDUAL AJCC CANCER TYPES IN THE CCGA STUDY WAS LOW AND/OR UNREPORTED ACROSS MULTIPLE CANCER TYPES FOR WHICH GRAIL CLAIMS THAT GALLERI CAN DETECT A SIGNAL.....749

J. GRAIL HAS NOT GENERATED SUFFICIENT CLINICAL EVIDENCE TO SUPPORT A 50-CANCER DETECTION CLAIM BEFORE THE FDA.....753

Complaint Counsel’s Proposed Conclusions of Law

Complaint Counsel’s Witness Index

Complaint Counsel’s Exhibit Index

## I. BACKGROUND

### A. ILLUMINA

1. Illumina is a publicly traded, for-profit Delaware corporation founded in 1998, with its headquarters in San Diego, California. (PX0061 at 004 (Illumina 2020 Form 10-K)).
2. Illumina's principal product offerings are short-read NGS instruments used for DNA sequencing and associated consumables, analytical software, and ancillary service contracts. (PX0061 at 005 (Illumina 2020 Form 10-K)).
3. The majority of Illumina's revenue comes from the sale of NGS instruments and consumables. (PX0061 at 007-08 (Illumina 2020 Form 10-K)).

#### 1. Illumina Is a Dominant Provider of Next Generation Sequencing Platforms

4. Illumina describes itself as "the global leader in sequencing- and array-based solutions for genetic and genomic analysis." (PX0061 at 005 (Illumina 2020 Form 10-K)).
5. Illumina has "an extensive intellectual property portfolio," including ownership or exclusive licenses to over 900 U.S. patents and 600 pending U.S. patent applications. (PX0061 at 009 (Illumina 2020 Form 10-K)).
6. [REDACTED] (PX5027 (Illumina) at 009 [REDACTED] (*in camera*)).
7. [REDACTED] } (PX5027 (Illumina) at 009 [REDACTED] (*in camera*)).
8. Illumina sells a variety of NGS sequencing instruments, including the "high-throughput" NovaSeq model; "mid-throughput" NextSeq models; and "low-throughput" MiSeq, MiniSeq, and iSeq models. (PX0091 (Illumina) at 011-013 (Illumina Source Book, August 2020); *see* PX0114, Illumina Sequencing Platforms, <https://www.illumina.com/systems/sequencing-platforms.html> (last visited Feb. 4, 2022) (listing Illumina sequencing platforms).
9. Illumina's instruments are "based on [Illumina's] proprietary technologies." (PX0061 at 007 (Illumina 2020 Form 10-K)).
10. [REDACTED] } (PX6056 (Illumina) at 018 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

11. In 2020, Illumina’s instrument sales accounted for 13 percent of Illumina’s total revenue. (PX0061 at 007 (Illumina 2020 Form 10-K)).
12. Illumina offers consumables, which include reagents, flow cells, and microarrays. (PX0061 at 007 (Illumina 2020 Form 10-K)).
13. There are two primary types of consumables involved in NGS: library preparation or sample preparation reagents, and core consumables. (PX7045 (Chudova (Guardant) IHT at 83-84)).
14. Library preparation reagents are used to prepare a sample for testing, for example by replicating DNA of interest so that it may be more easily examined. (PX7040 (Getty (Guardant) IHT at 63-64)).
15. Core consumables are reagents that must be used together with an instrument to implement a sequencing assay, such as a flow cell. (PX7063 (Berry (Illumina) IHT at 28); PX7045 (Chudova (Guardant) IHT at 83-84)).
16. Dr. Aravanis of Illumina testified that consumables are “the materials that are actually consumed in a sequencing run” and explained that for “every sequencing run you need a new set of consumables, but you use the same instrument.” (Aravanis (Illumina) Tr. 1845-46).
17. According to Illumina’s Nicole Berry, Illumina is “the only supplier of the core consumables that run on [Illumina’s] instrumentation.” (PX7063 (Berry (Illumina) IHT at 28)).
18. Illumina’s consumables are “based on [Illumina’s] proprietary technologies.” (PX0061 at 007 (Illumina 2020 Form 10-K)).

## 2. Formation of Grail

### a) Illumina Began Researching MCED Test as Part of a Larger Exploration of cfDNA Technology

19. In early 2013, Illumina acquired Verinata Health, Inc. (“Verinata”). (DeSouza (Illumina) Tr. at 2420).
20. Verinata was a provider of non-invasive prenatal tests that utilized NGS technology. (Chudova (Guardant) Tr. at 1143-44).
21. Around the time of Illumina’s acquisition of Verinata, NIPT companies including Natera and Sequenom had observed cancer signals when performing NIPTs. (PX7060 (Naclerio (Illumina) IHT at 33-34, 35-37)).
22. Subsequent to its acquisition of Verinata, Illumina observed cancer signals in its NIPT tests. (PX2184 (Illumina) at 001 (E-mail from R. Klausner, Illumina, to N. Naclerio, Illumina, Mar. 8, 2014)).

23. In mid-2015, a team within Illumina including Jay Flatley assembled a presentation proposing the creation of a new company to develop a blood-based cancer detection test. (PX2007 (Illumina) at 013 (Illumina, ScreenCo Opportunity Overview, July 30, 2015)). The presentation stated: “Illumina is uniquely positioned to pioneer this field today. Forward pricing to ScreenCo enables the R&D to sequence at depths that are cost-prohibitive to others[.]” (PX2007 (Illumina) at 013 (Illumina, ScreenCo Opportunity Overview, July 30, 2015)).

b) Illumina Formed Grail in 2015-2016

24. Illumina’s leadership considered several reasons to form Grail as a separate company, rather than a unit within Illumina. (PX2005 (Illumina) at 012 (Illumina, ScreenCo: Early Cancer Detection on a Global Scale, 2015)). According to a 2015 Illumina presentation, forming a new startup would enable Grail to “retain[] and attract[] best-in-class people through equity, culture, and quality of the science.” (PX2005 (Illumina) at 012 (Illumina, ScreenCo: Early Cancer Detection on a Global Scale, 2015)).

25. In a July 14, 2015, e-mail, Rick Klausner, Illumina’s Chief Medical Officer, wrote to other Illumina executives that creating a separate company would also protect Illumina. (PX2006 (Illumina) at 001 (E-mail from R. Klausner, Illumina, to M. Stapley et al., Illumina, July 14, 2015)).

26. Klausner wrote that creating a separate company would protect Illumina by “[n]ot competing with [Illumina’s] customers”; “[b]eing able to fail without consequences to Illumina stock”; and “[b]eing able to create a novel clinical and consumer brand.” (PX2006 (Illumina) at 001 (E-mail from R. Klausner, Illumina, to M. Stapley et al., Illumina, July 14, 2015)).

27. Forming a separate company would allow Illumina to attract additional investment for Grail. (PX2006 (Illumina) at 001 (E-mail from R. Klausner, Illumina, to M. Stapley et al., Illumina, July 14, 2015)).

28. Illumina’s leadership assessed that creating a separate company would allow Grail to be “more nimble”: “make decisions more quickly [and] . . . change directions more quickly.” (PX7089 (Naclerio (Illumina) Dep. at 253)).

29. In January 2016, Illumina formed Grail as a separate corporate entity. (PX2543 (Illumina) at 001 (Illumina, Grail FAQs, Jan. 11, 2016)). At the time of Grail’s creation, Illumina held a controlling stake in Grail. (PX2543 (Illumina) at 001 (Illumina, Grail FAQs, Jan. 11, 2016)).

30. While Illumina controlled Grail, Illumina provided Grail with “forward pricing.” (PX7089 (Naclerio (Illumina) Dep. at 250)). “Forward pricing” meant that Illumina charged Grail what Illumina expected its prices to be a number of years in the future. (PX7089 (Naclerio (Illumina) Dep. at 250)). The impact of providing forward pricing to Grail was that Illumina gave Grail discounts on reagents. (PX7089 (Naclerio (Illumina) Dep. at 251)). Dr. Naclerio negotiated Grail’s initial supply agreements for Illumina. (PX7089 (Naclerio (Illumina) Dep. at 250)). Dr. Naclerio stated that it would have been difficult for Grail to

- develop its MCED test without forward pricing. (PX7060 (Naclerio (Illumina) IHT at 201-202)).
31. Illumina formed Grail or “ScreenCo” because the “complexity of cancer biology, number of cancers, combined with multiple technical approaches [would] require significant R&D investment.” (PX2005 (Illumina) at 018 (ScreenCo: Early Cancer Detection on a Global Scale Presentation, 2015)).
  32. Illumina incorporated Grail in Delaware in September 2015 as a wholly-owned subsidiary of Illumina. (PX4082 (Grail) at 167, 211 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
  33. Grail subsequently raised \$100 million in Series A financing from investors including Illumina, Arch Ventures, Bill Gates, and Jeff Bezos. (RX0667 (Illumina) at 002 (Email from J. Flatley, Illumina, to W. Rastetter, Illumina, attaching “Illumina Forms New Company to Enable Early Cancer Detection via Blood Based Screening,” Jan. 10, 2016; PX2069 (Illumina) at 005 (Python Board Approval, Dec. 20, 2015)).
  34. By forming Grail, Illumina assessed that it could “capitalize on [the] screening market years earlier AND own a substantial portion of the value created.” (PX2069 (Illumina) at 018 (Python Board Approval, Dec. 20, 2015)).
  35. [REDACTED] (PX2069 (Illumina) at 005-006 (Python Board Approval, Dec. 20, 2015) (*in camera*)).
  36. In an internal 2015 document, Illumina identified preferential, low-cost access to Illumina sequencing technology as a competitive advantage for Grail: Grail “is uniquely positioned to pioneer this field . . . at depths that are cost prohibitive for others.” (PX2005 (Illumina) at 009 (ScreenCo: Early Cancer Detection on a Global Scale, 2015); *see* PX2069 (Illumina) at 018 (Python Board Approval, Dec. 20, 2015) (identifying the “cost of sequencing” as the first among four “most significant barriers and drivers of liquid biopsy innovation and adoption”)).
  37. Illumina initially offered a 75 percent discount on Illumina products for use in Grail’s “Foundational Study and commercial screening.” (PX2557 (Illumina) at 017 (Minutes of the Meeting of the Board of Directors of Illumina, Inc., Dec. 20, 2015)).
  38. Illumina forecast that the 75 percent discount offered to Grail would generate approximately “\$100M savings to Python [Grail] over [the] first 3 years.” (PX2557 (Illumina) at 017 (Minutes of the Meeting of the Board of Directors of Illumina, Inc., Dec. 20, 2015)).
  39. As set forth in Section VII.D.1. below, contemporaneous statements and testimony from Illumina executives as well as ordinary course documents show that Illumina identified tools that could favor its then-subsiary Grail relative to its rivals and that the Illumina-Grail relationship changed from collaborator to customer following the spinoff of Grail.



### 3. Spinoff of Grail (Reducing Ownership to Less Than 50 Percent)

40. [REDACTED] } (PX4082 (Grail) at 211 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, Morgan Stanley, attaching Grail 2020 S-1/Amended, Sept. 2020); PX6049 (Grail) at 103 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
41. [REDACTED] } (PX6049 (Grail) at 103 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
42. [REDACTED] } (PX0054 (Grail Closes Over \$900 Million Initial Investment in Series B Financing to Develop Blood Tests to Detect Cancer Early, Mar. 1, 2017 (*in camera*)); *see also* deSouza (Illumina) Tr. 2202).
43. [REDACTED] (deSouza (Illumina) Tr. 2202, 2453; PX6049 (Grail) at 103 (Narrative Response to Second Request, Mar. 1, 2021 (*in camera*)); PX2541 (Illumina) at 004 (Interim Review: K2-Grail, Feb. 2, 2017) (*in camera*)).
44. Illumina sold Grail to outside investors in 2017 because the amount of investment required to develop Grail’s MCED test was “untenable.” (PX7057 (Flatley (Illumina) IHT at 157-60)).
45. Illumina CEO Francis deSouza testified that Illumina’s 2017 reduction of its interest in Grail changed Illumina’s relationship from an affiliate relationship to a customer relationship. (DeSouza (Illumina) Tr. 2207).
46. After the 2017 financing round, Illumina ceased providing special discounts to Grail. (DeSouza (Illumina) Tr. 2207).
47. An Illumina investor Q&A document reviewed by Jay Flatley states that Illumina’s reduction of its stake in Grail “actually leveled the playing field” for Illumina’s other customers. (PX2406 (Illumina) at 005 (E-mail from J. Flatley, Illumina, to F. deSouza et al., Illumina, Jan. 2, 2017)).
48. Prior to Illumina’s reduction in its interest in Grail, “[Grail] had access to technology and pricing that was preferential to [Illumina’s] customers.” (PX2406 (Illumina) at 005 (E-mail from J. Flatley, Illumina, to F. deSouza et al., Illumina, Jan. 2, 2017)).
49. After Illumina’s reduction of its stake in Grail, Grail had “access to technology on [the] same terms and price as [Illumina’s] other large customers.” (PX2406 (Illumina) at 005 (E-mail from J. Flatley, Illumina, to F. deSouza et al., Illumina, Jan. 2, 2017)). The Illumina Q&A document states that Illumina “believe[d] that this [would] accelerate the liquid biopsy market for all.” (PX2406 (Illumina) at 005 (E-mail from J. Flatley, Illumina, to F. deSouza et al., Illumina, Jan. 2, 2017)).

50. By 2017, Grail had expanded its clinical trials from one study involving 50,000 individuals to five clinical trials involving over a million individuals. (PX2149 (Illumina) at 002-003 (Email from M. Stapley, Illumina, to D. Moriarty, Illumina, attaching Grail white paper, Sep. 24, 2016)).
51. As a result of Grail expanding its clinical trials, Grail's research and development projections moved back by two years and its associated costs increased from approximately \$400 million to \$1.5 billion. (PX7057 (Flatley (Illumina) IHT at 158-159)).
52. According to former CEO and Board Chairman, Mr. Jay Flatley, in light of Illumina's control of Grail, Grail's increased spending without corresponding revenues would have significantly diluted Illumina's reported earnings. (PX7079 (Flatley (Illumina) Dep. at 146-147)).
53. According to former Illumina CEO and board chairman Jay Flatley, Illumina's board determined that that its shareholders would not have tolerated this magnitude of dilution from Grail spending without corresponding revenues. (PX7057 (Flatley (Illumina) IHT at 159)).
54. In a November 4, 2016 email, Mr. Flatley explained to a Grail executives that "[Illumina had] concerns that relinquishing control of Grail could result in the "[l]oss of [h]uge [u]pside potential in market value of GRAIL," the "[l]oss of [r]oyalty future value to [Illumina]," and a potential "[i]mpact to [Illumina's] external credibility." (PX2411 (Illumina) at 002 (Email from J. Flatley, Illumina, to J. Huber, Grail, et al., Nov. 4, 2016)).
55. Francis deSouza stated publicly in June 2017:

There are 70-plus players now in the liquid biopsy space. We want to encourage them to look at all different avenues because this is important and the outcome's terrific for mankind. There are different points of view. There are companies that believe it's going to be a combination of ultra-deep screening of the blood samples plus tissue, whole transcriptome analysis to identify tissue of origin. And to be honest, I think people are approaching it slightly differently and the market will sort of determine where the biology is and what the right answer is. In every case though, we're talking about a lot of sequencing.

(PX0376 at 007 (Illumina Inc. at Goldman Sachs Global Healthcare Conference, FD (Fair Disclosure) Wire, Conference Call Transcript, June 13, 2017)).
56. At the same conference, deSouza stated of the liquid biopsy market: "[W]e want to encourage that market because that market, I think, is very promising from a patient perspective, but it uses a lot of sequencing." (PX0376 at 007 (Illumina Inc. at Goldman Sachs Global Healthcare Conference, FD (Fair Disclosure) Wire, Conference Call Transcript, June 13, 2017)).
57. Mr. Flatley testified that, prior to the spin-off of Grail, Illumina was hesitant to "go after markets . . . using a subsidiary of Illumina . . . that could compete more favorably with

existing customers [Illumina] had in the marketplace.” (PX7057 (Flatley (Illumina) IHT at 166)).

58. According to Illumina’s former CEO and board member Jay Flatley, Illumina determined that its customers might not want to participate in markets where Illumina had a presence, in part “because they’d believe that Illumina could always underprice them if we wanted to.” (PX7057 (Flatley (Illumina) IHT at 167)).

59. In a 2017 presentation to Sands Capital Management, Illumina told investors “We spun out Grail to encourage investment into many different NGS-based companies focused on early cancer detection to have as many shots on goal as possible.” (PX2561 (Illumina) at 017 (Email from J. Cunningham, Illumina, to F. deSouza, Illumina, Oct. 30, 2020, attaching Sands Capital Management Call); deSouza (Illumina) Tr. 2204-5).

60. [REDACTED] } (Respondents’ Pretrial Brief at 2, Aug. 18, 2021; *see also* PX4291 (Grail [REDACTED] (in camera) [REDACTED] ).

61. Illumina stated in internal Q&A bullets that divesting Grail would “accelerate the liquid biopsy market for all.” (PX2406 (Illumina) at 005 (email from J. Flatley, Illumina, to E. Endicott, Illumina, Jan. 2, 2017, attaching Illumina/Grail Q&A, Jan. 2, 2017)).

62. [REDACTED] } (RX1371 (Illumina) at 010–12 [REDACTED] (in camera); PX6049 (Grail) at 031 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (in camera)). [REDACTED] (RX1371 (Illumina) at 010–12 [REDACTED] (in camera)).

63. As noted in Illumina’s Board Minutes, when Illumina owned a majority stake in Grail Illumina provided Grail with preferential terms and agreed not to “launch, invest in, or provide special discounts to competitive business[es].” (PX2557 (Illumina) at 017 (Minutes of the Meeting of the Board of Directors of Illumina, Inc., Dec. 20, 2015); PX2541 (Illumina) at 008 (Interim Review K-2 Grail presentation, Feb. 2, 2017)).

64. As an independent company, Grail will move from a “collaborator” in assay development and software and data analysis to merely a “customer.” (PX2541 (Illumina) at 008 (Interim Review K-2 Grail presentation, Feb. 2, 2017)).

65. Prior to Illumina spinning Grail out, Illumina treated Grail as a “collaborator” co-developing Grail’s project development process, assay development workflow, software

and data analysis, and designed a kit specially for Grail. (PX2541 (Illumina) at 008 (Interim Review K-2 Grail presentation, Feb. 2, 2017)).

66. Illumina’s ordinary course documents charted the “[c]hanging business dynamic” between Illumina and Grail after the spinoff. The “[c]hanging business dynamic will result in Illumina functioning as a supplier compared to a product development partner,” noting that Grail will shift from being a “collaborator” to a “customer.” In this relationship, Illumina would limit their assistance in Grail’s project development process, assay development workflow, and software and data analysis. (PX2541 (Illumina) at 008, 010 (Interim Review K-2 Grail presentation, Feb. 2, 2017 (“Illumina and Grail no longer collaborating on developing [library prep] and sequencing kits”))).
67. After the spinoff, Illumina provided Grail “RUO kits” instead of the customized kits Grail was originally receiving. (PX2541 (Illumina) at 008, 014 (Illumina, Interim Review K-2 Grail presentation, Feb. 2, 2017)).

68. [REDACTED] } (Berry (Illumina) Tr. 988 (*in camera*)).

**B. GRAIL**

69. Grail’s principal office and laboratory is located in Menlo Park, CA. (PX4082 (Grail) at 130 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
70. Aaron Freidin, Grail SVP of Finance, testified that Grail has completed four separate rounds of financing. (Freidin (Grail) Tr. 3015-16).
71. [REDACTED] } (PX4082 (Grail) at 086 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); Freidin (Grail) Tr. 3015-16; PX5023 (Illumina) at 003 (Illumina, Project Grail, Phil Febbo & Corporate Development, Mar. 2020) (*in camera*)).
72. [REDACTED] } (PX5045 (Grail) at 014 (Grail, Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).
73. Grail has employees across a diverse range of functions including R&D, sales, market access, and government and regulatory affairs. (RX0874 (Grail) at 001 (Grail Organizational Structure, Aug. 26, 2020)).

**1. Grail’s Galleri MCED Test**

74. Grail’s flagship test is its MCED test, called Galleri. (RX3256 (Grail, *Our Products*, <https://grail.com/our-products>) (last visited Aug. 12, 2021); RX3255 (Grail, *The Galleri Test*, <https://www.galleri.com/the-galleri-test>) (last visited Aug. 12, 2021)).

a) Galleri Is an MCED Test Designed to Be Used by Asymptomatic Individuals

75. [REDACTED] } (PX6049 (Grail) at 012 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*); see also PX4572 (Grail) at 006, 032 (Grail, Early Cancer Detection: Investor Presentation, Dec. 2020) (*in camera*)).
76. Dr. Ofman testified that the Galleri test is intended to be used as a screening test for asymptomatic populations. (Ofman (Grail) Tr. 3431).
77. [REDACTED] } (RX3255 (Grail, *The Galleri Test*, <https://www.galleri.com/the-galleri-test>) (last visited Aug. 12, 2021); (Jamshidi (Grail) Tr. 4042-43 (*in camera*)).
78. [REDACTED] } (Jamshidi (Grail) Tr. 4032 (*in camera*)).
79. Grail claims that Galleri has the ability to detect over 50 cancers from a single blood draw. (RX3256 (Grail, *Our Products*, <https://grail.com/our-products>) (last visited Aug. 12, 2021); RX3255 (Grail, *The Galleri Test*, <https://www.galleri.com/the-galleri-test>) (last visited Aug. 12, 2021); see *infra* Section X, Appendix B (Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population))).
80. Grail has not presented clinical evidence that Galleri can provide “early detection” of more than 50 cancer types. (See Section X, Appendix B (Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population) below)).
81. To date, Grail has presented clinical evidence that the Galleri test can detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Interim Results of Pathfinder, June 4, 2021) (showing seven cancers as being detected in stages one through three: head and neck, liver/bile duct, lung, lymphoma, ovary, pancreas, and small intestine); see *generally* Section X, Appendix B (Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population) below)).
82. [REDACTED] } (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
83. [REDACTED] } (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

b) Galleri Launched as an LDT in April 2021

84. [REDACTED] (PX4171 (Grail) at 030 (Grail Board of Directors Meeting Presentation, Aug. 20, 2019) (*in camera*)).
85. [REDACTED] (PX4213 (Grail) at 005 [REDACTED] (*in camera*); see PX4160 (Grail) at 094 (Grail, Board Session Meeting Materials, Nov. 10, 2020) (*in camera*) ([REDACTED])).
86. [REDACTED] (PX6061 (Grail) at 013 (Grail, Responses and Objections to the Federal Trade Commission’s First Set of Interrogatories, May 3, 2021) (*in camera*)).
87. [REDACTED] (PX6049 (Grail) at 020 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*); see also PX5044 (Grail) at 003 (Grail LRP Review, Aug. 20, 2020) (*in camera*) ([REDACTED])).
88. To sell the Galleri test as an LDT, Grail is targeting large, self-insured employers; concierge medicine practices; executive health programs; and other physicians whose clients have the financial means to enroll in preventative health programs. (PX4082 (Grail) at 009, 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
89. [REDACTED] (PX6061 (Grail) at 043 (Grail, “Responses and Objections to the Federal Trade Commission’s First Set of Interrogatories,” May 3, 2021) (*in camera*)).
90. As of trial, Grail [REDACTED] (Ofinan (Grail) Tr. 3372, 3374-75 (*in camera*); see also Bishop (Grail) Tr. 1332-33 ([REDACTED])).

91. [REDACTED] } (Della Porta (Grail) Tr. 464; Ofman (Grail) Tr. 3372 (*in camera*); *see also* Bishop (Grail) Tr. 1333 ([REDACTED])).

92. At trial, Illumina and Grail’s CEOs testified that Grail’s Galleri test cost \$949 out of pocket. (Bishop (Grail) Tr. 1322, 1404; deSouza (Illumina) Tr. 2342).

93. In the September 21, 2020 investor call where Illumina CEO Francis deSouza announced that Illumina would acquire Grail, deSouza stated that the price of Galleri would start at \$1,200. (PX2575 (Illumina) at 070 (Illumina M&A Call, Sept. 21, 2020)).

94. Grail Chief Medical Officer Joshua Ofman testified: “we don’t expect that large U.S. payers are going to provide coverage for the [Galleri] test without FDA approval.” (Ofman (Grail) Tr. 3319-20).

95. [REDACTED] (Ofman (Grail) Tr. 3352-54 (*in camera*)) ([REDACTED]); PX4209 (Grail) at 004-008 (Grail, Market Access Strategy, June 2020) (*in camera*) ([REDACTED])).

96. [REDACTED] } (PX7062 (Kollu (Grail), IHT at 166-167) (*in camera*)).

97. Grail’s Chief Medical Officer, Dr. Josh Ofman, testified at trial that Grail has assembled a capable team in Washington, D.C., to advocate for accelerated Medicare coverage of Galleri and MCED tests. (Ofman (Grail) Tr. 3356-57, 3450).

c) [REDACTED] }

98. [REDACTED] (Bishop (Grail) Tr. 1441 (*in camera*)).

99. [REDACTED] (PX5044 (Grail) at 006-007 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

100. [REDACTED] (PX5044 (Grail) at 010-11 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

101. [REDACTED]

[REDACTED] } (Bishop (Grail) Tr. 1441-43 (*in camera*)).

102. [REDACTED] } (PX5044 (Grail) at 023 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

103. [REDACTED] } (PX5044 (Grail) at 024 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

104. [REDACTED] } (PX4016 (Grail) at 025 (Grail, Grail Strategy Planning Roadmap (Workshop #2), Sept. 2, 2020) (*in camera*)) ([REDACTED]); PX4491 (Grail) at 007, 035-043 (Grail, Board of Directors Meeting, Apr. 30, 2019) (*in camera*)).

105. [REDACTED] (PX5044 (Grail) at 003 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

106. [REDACTED] } (PX5044 (Grail) at 003 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

107. [REDACTED] (Ofman (Grail) Tr. 3351 (*in camera*); PX7069 (Bishop (Grail) IHT at 193-94); PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

108. [REDACTED] (Ofman (Grail) Tr. 3351 (*in camera*); see PX7069 (Bishop (Grail) IHT at 193-4); PX4082 (Grail) at 011 (Email attaching Grail 2021 S-1/Amended, Sept. 2020); see also Febbo (Illumina) Tr. 4430 (*in camera*) ([REDACTED])).

109. [REDACTED] } (PX5044 (Grail) at 018 (Grail LRP Review, Aug. 20, 2020) (*in camera*)).

d) [REDACTED]

110. Dr. Joshua Ofman, Grail’s Chief Medical Officer, testified that the clinical study program Grail has launched as an independent company is “one of the largest I’ve seen.” (Ofman (Grail) Tr. 3445).



111. As of September 2021, Grail has enrolled over 130,000 participants in clinical studies. (PX0390 (ClinicalTrials.gov Search Results for “Grail,” Sept. 23, 2021)).
112. Grail has partnered with the Mayo Clinic, Cleveland Clinical, and Henry Ford Health System for clinical studies. (Qadan (Illumina) Tr. 4263).
113. Grail began its clinical study program with the Circulating Cell-Free Genome Atlas (“CCGA”) study, which Grail initiated “after Grail was spun out of Illumina and their – the R&D was externalized.” (Ofman (Grail) Tr. 3291-92).
114. [REDACTED] } (PX4430 (Grail) at 021 [REDACTED] (*in camera*); PX6049 (Grail) at 015 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
115. In observational studies, test results are not returned to the patients but rather, the patients are tracked over the duration of the study, and Grail compares the results of its tests with the patients’ cancer diagnoses at the conclusion of a predetermined period. (PX7092 (Ofman (Grail) Dep. at 255-257)).
116. [REDACTED] } (PX6049 at 015 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
117. The CCGA study comprises three substudies: CCGA-1, CCGA-2, and CCGA-3. (PX7069 (Bishop (Grail) IHT at 79)).
118. Grail used CCGA-1 and CCGA-2 to develop Galleri and gather information about Galleri’s performance. (PX7069 (Bishop (Grail) IHT at 80); PX6049 (Grail) at 016 (Grail, Narrative Response to Second Request, Mar. 1, 2021 ( [REDACTED] [REDACTED] } ) (*in camera*)).
119. [REDACTED] } (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
120. [REDACTED] } (PX7092 (Ofman (Grail) Dep. at 252); PX6049 (Grail) at 016 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
121. [REDACTED] (PX6049 (Grail) at 015 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
122. [REDACTED]

[REDACTED]

} (RX3410 (National Institutes of Health, U.S. National Library of Medicine, The Circulating Cell-free Genome Atlas Study (CCGA), <https://clinicaltrials.gov/ct2/show/NCT02889978>) (last visited Jan. 3, 2022); PX6093 (Navathe Rebuttal Report) at 026-29 (*in camera*)).

123. Shortly after Grail launched the CCGA study, it launched “two very large cohort studies,” STRIVE and SUMMIT. (Ofman (Grail) Tr. 3293).

124. [REDACTED] (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

125. [REDACTED] (PX7092 (Ofman (Grail) Dep. at 255-256); *see* PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

126. [REDACTED] (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

127. [REDACTED] } (Ofman (Grail) Tr. 3294-95; PX4430 (Grail) at 021 (*in camera*); PX7092 (Ofman (Grail) Dep. at 256-257); PX6049 (Grail) at 017-18 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

128. [REDACTED] } (PX4430 (Grail) at 021 (*in camera*); PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

129. [REDACTED] (PX6049 (Grail) at 018 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

130. [REDACTED]

- [REDACTED] } (PX6049 at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
131. Grail's PATHFINDER 1 study is an interventional, real-world, clinical practice study of 6,600 individuals with no suspicion of cancer. (Ofman (Grail) Tr. 3293).
132. [REDACTED] } (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
133. Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of stage one through three cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Interim Results of Pathfinder, June 4, 2021) (showing 7 cancers as being detected in stages one through three: head and neck, liver/bile duct, lung, lymphoma, ovary, pancreas, and small intestine).
134. Accordingly, the PATHFINDER test does not provide clinical evidence of Galleri's ability to screen for more than 50 types of cancer in an asymptomatic screening population. (Cote Tr. 4000-02).
135. [REDACTED] (PX4074 (Grail) at 031 (Grail, Science, Medicine, and Technology Board Subcommittee Meeting Pre-Read, Mar. 2, 2020) (*in camera*)).
136. [REDACTED] (Ofman (Grail) Tr. 3293-94; PX7092 (Ofman (Grail) Dep. at 123); PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
137. [REDACTED] (PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
138. [REDACTED] } (PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
139. [REDACTED] (PX4430 (Grail) at 022 [REDACTED] (*in camera*); PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)) ([REDACTED] }).

140. [REDACTED] (PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

141. According to Dr. Patricia Deverka, one of Respondents’ retained expert witnesses, the UK NHS study, as a “pragmatic clinical trial,” will generate “important evidence of clinical utility” of the Galleri test. (RX6001 (Deverka Trial Dep. at 98)).

142. Dr. Ofman testified that the U.K. NHS study is the “largest, real-world, what we call a pragmatic, randomized clinical trial” ever in genomics. (Ofman (Grail) Tr. 3293-94; *see also* Freidin (Grail) Tr. 3008, 3161).

143. Grail negotiated its agreement with NHS before Illumina acquired Grail. (Freidin (Grail) Tr. 3161; *see also* Qadan (Illumina) Tr. 4263-64 (testifying that Grail accomplished its partnership with NHS as an independent company without assistance from Illumina)).

144. [REDACTED] } (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

145. [REDACTED] } (PX4430 (Grail) at 021-022 [REDACTED] (*in camera*)).

146. [REDACTED] (PX6049 (Grail) at 017 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

147. [REDACTED] } (RX3134 (National Institutes of Health, U.S. National Library of Medicine, Development Of A Blood Test To Improve The Performance Of Breast Cancer Screening, <https://clinicaltrials.gov/ct2/show/NCT03372902>) (last visited Jan. 3, 2022); PX6093 (Navathe Rebuttal Report) at 026-29 (*in camera*); PX6049 (Grail) at 020 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

148. [REDACTED] (PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

149. [REDACTED] (PX6049 (Grail) at 019 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)) ( [REDACTED]

[REDACTED] })).

2. [REDACTED] }

150. [REDACTED] } (PX7069 (Bishop (Grail) IHT at 45) (*in camera*)).

151. [REDACTED] } (PX6049 (Grail) at 013 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

152. Diagnostic Aid to Cancer (“DAC”) tests are designed to confirm a cancer diagnosis by using genomic data to predict the likelihood that a patient has a particular cancer. (PX7069 (Bishop (Grail) IHT at 69-70); PX7072 (deSouza (Illumina) IHT at 160-61)).

153. [REDACTED] } (PX6049 (Grail) at 021 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

154. [REDACTED] } (PX7069 (Bishop (Grail) IHT at 45) (*in camera*)).

155. Minimal Residual Disease (“MRD”) tests are designed to determine whether remnants of cancer remain in a patient who has been treated for cancer. (PX7092 (Ofman) Dep. at 94); PX7069 (Bishop) IHT at 71-72); PX6049 (Grail) at 013 (Grail, Narrative Response to Second Request, Mar. 1, 2021) ([REDACTED] } (*in camera*)).

156. [REDACTED] See (PX7069 (Bishop (Grail) IHT at 45, 69-72) (*in camera*)).

157. [REDACTED] (PX6049 (Grail) at 013 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

158. [REDACTED] } (PX6049 (Grail) at 021 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

### 3. Grail's Intellectual Property Holdings


159. Grail owns or co-owns “more than 170 pending patent applications globally, including more than 90 pending U.S. non-provisional and provisional patent applications.” (PX4082 (Grail) at 128 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
160. Grail holds “exclusive licenses to more than 230 issued or granted patents and more than 200 pending patent applications globally, including 30 issued U.S. patents.” (PX4082 (Grail) at 128 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
161. Grail has entered into five license agreements with the Chinese University of Hong Kong, pursuant to which the Chinese University of Hong Kong granted Grail “exclusive, worldwide intellectual property licenses . . . for the use of certain nucleic acid sequencing and analysis technologies in all fields under one license and in all field except prenatal diagnostics, prognostications, or analysis under four licenses.” (PX4082 (Grail) at 129 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
162. Grail's acquisition of Cirina was a building block for its patent portfolio: “In June 2017, we acquired Hong Kong-based Cirina Limited, founded on the basis of the work of Dr. Dennis Lo, a pioneer in clinical applications of cfDNA sequencing, which provided us with a number of patents and exclusive licenses to patents related to the use of cfDNA for early detection of cancer.” (PX4082 (Grail) at 086 (Email attaching Grail 2020 S-1/Amended, Sept. 2020))
163. [REDACTED] (Freidin (Grail) Tr. 3079) (*in camera*).
164. [REDACTED] (Freidin (Grail) Tr. 3079-80) (*in camera*).
165. A May 2017 Grail board presentation stated that the acquisition of Cirina will “[e]nable GRAIL to enforce early IP against GRAIL's competitors.” (PX4620 (Grail) at 015 (Project Knight – Board Update II, May 10, 2017)).
166. The May 2017 Grail board presentation recognized how the Cirina IP acquisition prevents Grail from the burden of an “expensive litigation/expensive settlement if GRAIL were to infringe.” (PX4620 (Grail) at 015 (Project Knight – Board Update II, May 10, 2017)).
167. The May 2017 Grail board presentation stated that “Cirina's Intellectual Property assets protect GRAIL's commercial strategy and may constrain competitors.” (PX4620 (Grail) at 004 (Project Knight – Board Update II, May 10, 2017)).
168. The Cirina transaction provided Grail with exclusive access to additional IP when Dr. Dennis Lo agreed to join Grail's Scientific Advisory Board, providing Grail with “rights to future Lo IP also going to GRAIL (rather than competitors) – e.g., joining forces with Lo, rather than competing with Lo[.]” (PX4620 (Grail) at 015 (Project Knight – Board Update II, May 10, 2017)).

169. Grail’s pre-Cirina IP related to specific barcode techniques. (PX4620 (Grail) at 015 (Project Knight – Board Update II, May 10, 2017)).

**4. Grail Prepared to Go Public Prior to Acquisition**

170. Grail successfully raised \$300 million as part of an “oversubscribed” Series C financing round in May 2018, bringing its total equity raised to more than \$1.5 billion. (PX0051 at 001 (Grail Announces \$300 Million Raised in Oversubscribed Series C Financing, May 21, 2018)).

171. Grail successfully raised \$390 million as part of a Series D financing round in May 2020, bringing its total equity raised to more than \$1.9 billion. (PX0052 at 001-002 (Grail Announces \$390 Million Series D Financing, May 6, 2020)).

172.   
 (PX4341 (Grail) at 001 (Email from H. Bishop (Grail) to B. Nelson (Grail), Aug. 21, 2020) (*in camera*)).

173. Matthew Strom, Morgan Stanley Managing Director in the Healthcare Investment Banking Group, testified that Morgan Stanley was “the exclusive financial advisor to Grail” in its acquisition by Illumina. (Strom (Morgan Stanley) Tr. 3473).


174. Morgan Stanley was “tasked to help GRAIL negotiate the transaction with Illumina, evaluate potential alternatives, including an IPO, as well as complete due diligence and help the board think about valuation and put the transaction in context from a financial perspective for the board to -- other transactions as well as other alternatives.” (Strom (Morgan Stanley) Tr. at 3474).

175. Morgan Stanley was the lead underwriter for Grail’s planned IPO. (Strom (Morgan Stanley) Tr. 3591-92).

176. Morgan Stanley assisted Grail in preparing of its Form S-1, which is the registration statement filed by a private company that enables it to sell public securities. (Strom (Morgan Stanley) Tr. 3591-92).

177. Grail filed its S-1 registration statement on September 9, 2020. (PX0053 (Grail Announces Filing of Registration Statement for Proposed Initial Public Offering, Sept. 9, 2020)).

a)   
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178.   
 (PX4175 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

179. [REDACTED] (PX4175 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

180. [REDACTED] (Strom (Morgan Stanley) Tr. at 3565 (*in camera*)).

181. [REDACTED] (PX4175 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

182. [REDACTED] (PX4175 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

183. [REDACTED] (PX4175 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*); see also PX8463 (Morgan Stanley) at 007 [REDACTED] (*in camera*) ([REDACTED])).

184. [REDACTED] (PX4175 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*); see PX8463 (Morgan Stanley) at 007 [REDACTED] (*in camera*) ([REDACTED])).

185. [REDACTED] (PX4175 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*); see also PX8463 (Morgan Stanley) at 007 [REDACTED] (*in camera*) ([REDACTED])).



b) [REDACTED]  
[REDACTED]

186. [REDACTED] (Strom (Morgan Stanley) Tr. at 3532 (*in camera*)).

187. [REDACTED] } (PX4137 (Grail) at 008 (The Roundtable, Sep. 30, 2020); *see also* PX7108 (Freidin (Grail) Dep. at 54-55) (*in camera*)).

188. Because Illumina and Grail entered into an acquisition agreement on September 20, 2020, Grail never went public. (PX7108 (Freidin (Grail) Dep. at 113)).

c) [REDACTED]  
[REDACTED]

189. [REDACTED] } (Freidin (Grail) Tr. 3072 (*in camera*)).

190. [REDACTED] (Freidin (Grail) Tr. 3072 (*in camera*)).

191. [REDACTED] } (Freidin (Grail) Tr. 3073 (*in camera*)).

192. [REDACTED] } (Freidin (Grail) Tr. 3073-74 (*in camera*)).

193. Grail did not approach any other life sciences companies that have successfully obtained PMA approval for IVD tests about partnering or merging with Grail. (Ofman (Grail) Tr. 3447-49).

194. [REDACTED] (Strom (Morgan Stanley) Tr. at 3573-75 (*in camera*); PX8472 (Morgan Stanley) at 028 [REDACTED] (*in camera*)).

195. If the Illumina-Grail transaction is unwound, investors have expressed interest “in making a more significant investment in GRAIL should [GRAIL] choose to access the capital markets.” (*See, e.g.,* PX4468 (Grail) at 002 (Email from N. Cornell, Bluewater Life Science Advisors, to J. Craighead, Grail, Apr. 13, 2021)).

196. Grail’s VP of Investor Relations, John Craighead, told investors that Grail will be “well positioned for any outcome” with the Illumina transaction. (PX4468 (Grail) at 001 (Email from J. Craighead, Grail, to N. Cornell, Bluewater Life Science Advisors, Apr. 16, 2021)); see PX4467 (Grail) at 002 (Text message exchange between V. Demas, Grail, and H. Kiarie, Grail, Mar. 31, 2021) (noting that “we can still IPO” if the Proposed Acquisition falls through).

C. THE TRANSACTION

197. On September 20, 2020, Illumina entered into an Agreement and Plan of Merger to acquire Grail for total consideration of \$8 billion, consisting of \$3.5 billion in cash and \$4.5 billion in shares of Illumina common stock, subject to a collar. (PX0061 at 005 (Illumina 2020 Form 10-K); see also Bishop (Grail) Tr. 1353 (stating that the total transaction value for the Grail acquisition was approximately \$8 billion “[a]s measured by the common accounting standards”); deSouza (Illumina) Tr. 2215; PX5048 at 002-03 (Grail, Notification and Report Form, Oct. 9, 2020) (stating that on September 20, 2020, Respondents entered into an Agreement and Plan of Merger for Illumina to acquire all of Grail’s outstanding voting shares, for a combination of cash and stock consideration valued at about \$7.1 billion)).

198. [REDACTED] }  
(Freidin (Grail) Tr. 3070-71 (*in camera*)).

199. [REDACTED]  
[REDACTED] (Freidin (Grail) Tr. 3071 (*in camera*)).

200. Illumina consummated its acquisition of Grail on August 18, 2021. (deSouza (Illumina) Tr. 2234; Bishop (Grail) Tr. 1353; Berry (Illumina) Tr. 857).

201. Illumina filed an 8-K report with the Securities and Exchange Commission as a result of consummating the acquisition of Grail. (deSouza (Illumina) Tr. 2234).

202. Illumina has now paid Grail the \$8 billion consideration owed under the merger agreement. (deSouza (Illumina) Tr. 2239)

203. [REDACTED] }  
[REDACTED] (deSouza (Illumina) Tr. 2282 (*in camera*)).

204. “Once the deal closed,” Illumina eliminated patent-related royalties that Grail previously paid to Illumina. (deSouza (Illumina) Tr. 2358-59).

205. When Illumina completed its acquisition of Grail, Illumina immediately eliminated the royalty that Grail had been required to pay on all future sales. (Aravanis (Illumina) Tr. 1959).

1. [REDACTED]

206. [REDACTED] } (PX2488 (Illumina) at 009  
(in camera)).

207. Jay Flatley, Chairman of the Illumina Board at the time of the acquisition, testified that increasing shareholder value was one reason the Board approved the acquisition. (Flatley (Illumina) Tr. 4095-96). Mr. Flatley expects the acquisition to increase both revenue and profits once the Galleri test “got into the marketplace.” (Flatley (Illumina) Tr. 4096-97).

208. [REDACTED]  
(PX2316 (Illumina) at 008 (Email from J. Goswami, Illumina, to A. Qadan et al., Illumina, attaching “Board of Directors M&A Landscape,” Apr. 29, 2020) (in camera)).

209. Internal Illumina documents indicate that Illumina intends to use its acquisition of Grail to [REDACTED]  
(PX2465 (Illumina) at 003  
(in camera)).

210. Illumina’s Strategic Plan for 2021-2025 declares, [REDACTED]  
(PX2169 (Illumina) at 045 (Illumina, “Illumina Strategic Plan 2021-2025, Board Discussion Document,” Oct. 23, 2020) (in camera)).

211. According to Illumina’s internal documents, [REDACTED]  
} PX2465 (Illumina) at 003  
(in camera)).

212. [REDACTED] (PX2488  
(Illumina) at 009 (in camera)).

213. [REDACTED]

- [REDACTED] } (PX2488 (Illumina) at 009 [REDACTED] (in camera)).
214. [REDACTED] (PX2464 (Illumina) at 025, 036 (Illumina, April BoD M&A Strategy Presentation, Apr. 28, 2020) (in camera)).
2. [REDACTED] }
215. [REDACTED] (PX2055 (Illumina) at 005 (Grail Integration Planning Update, Oct. 22, 2020) (in camera); see also PX2008 (Illumina) at 015 (Board of Directors Strategic Plan, Nov. 4, 2020) (in camera) ([REDACTED])); PX5032 (Illumina) at 010 [REDACTED] (in camera) ([REDACTED])).
216. [REDACTED] (PX2464 (Illumina) at 031, 039 (April BoD M&A Strategy Presentation, Apr. 28, 2020) (in camera)).
217. In a September 2020 Illumina FAQ document relating to Illumina’s acquisition of Grail, an “Employee FAQ” section stated: “We do not expect material synergies to the transaction.” (PX2575 (Illumina) at 013 (E-mail from T. Friedman, Illumina, to J. Cunningham, Illumina, Sept. 29, 2020)).

**3. The Parties Closed the Transaction Despite the Possibilities of Fines, Reputation Consequences, and Other Government Enforcement Action**

218. Illumina closed the transaction despite knowing that doing so could result in the imposition of “fines, penalties, remedies or restrictions” by government or regulatory authorities. (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021)).
219. Illumina disclosed that consummating the transaction when it did could lead to “other adverse consequences to, among other things, its reputation[.]” (PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); see also deSouza (Illumina) Tr. 2236-37 (stating that Illumina decided to close the transaction despite the potential risk to its reputation)).
220. Illumina acknowledged in an SEC filing that:
- The European Commission had previously notified Illumina asserting that as a result of the Referral [of the transaction for European Union merger review under Article 22(1) of Council Regulation (EC) No 139/2004], pursuant to

Article 22(4) of the EU Merger Regulation, Illumina was prohibited from implementing the Acquisition (i) until the European Commission clears the Acquisition under the EU Merger Regulation or (ii) until the European Commission refuses the Referral, and therefore the European Commission's acceptance of the Referral continued the purported standstill on the completion of the Acquisition until such time as the European Commission completes its review and approves the Acquisition.

(PX0378 at 004 (Illumina Form 8-K, Aug. 18, 2021)).

221. Illumina understood that by consummating the transaction during the pendency of the European Commission's review, it would "likely" cause the European Commission to seek to fine Illumina:

As a result of Illumina's decision to proceed with the completion of the Acquisition during the pendency of the European Commission's review, the European Commission will likely seek to impose a fine on Illumina pursuant to Article 14(2)(b) of the EU Merger Regulation of up to 10% of Illumina's consolidated annual turnover.

(PX0378 at 005 (Illumina Form 8-K, Aug. 18, 2021); *see also* deSouza (Illumina) Tr. 2235 (stating that Illumina decided to close the transaction despite the potential fines from the European Commission)).

222. When Respondents closed the Acquisition despite a standstill order from the European Commission, Respondents promised to hold Grail separate from Illumina, meaning that Grail "will be run as a separate entity, and where it engages with Illumina, it will do so on an arm's length basis." (deSouza (Illumina) Tr. 2463; *see also* PX2851 (Illumina) (Hold-Separate Commitments, Aug. 18, 2021) (*in camera*) ( [REDACTED] ) (*in camera*)).

223. [REDACTED] (PX2851 (Illumina) at 001 (Hold-Separate Commitments) (*in camera*)).

224. Illumina publicly described its hold-separate commitment as "voluntarily offered." (PX0378 at 004 (Illumina Form 8-K, Aug. 18, 2021)).

225. [REDACTED]

[REDACTED] } (PX2851 (Illumina) at 002 (Hold-Separate Commitments) (*in camera*); see also PX0378 at 004 (Illumina Form 8-K, Aug. 18, 2021)).

226. On October 14, 2021, Illumina appointed its Chief Operations Officer, Bob Ragusa, as Chief Executive Offer of Grail. (PX0405, (Illumina Appoints Ragusa as Chief Executive Officer (CEO) of GRAIL, Oct. 14, 2021, <https://www.illumina.com/company/news-center/press-releases/press-release-details.html?newsid=2e72344d-ceaf-4453-868a-423516a4ba49> (last visited Oct. 25, 2021)).

## II. INDUSTRY BACKGROUND

### A. CANCER IS THE SECOND LEADING CAUSE OF DEATH IN THE UNITED STATES

227. Cancer is the second-leading cause of death in the United States. (PX4095 (Grail) at 005 (A New War on Cancer, Investor Presentation, July 2020); Nolan (Freenome) Tr. 2724; Conroy (Exact) Tr. 1735; see RX3030 at 003 (American Cancer Society, Cancer Facts & Figures 2019) (ACS estimated that over 1.7 million new cancer cases would be diagnosed in 2019 in the United States)).
228. Approximately 630,000 Americans die from cancer each year. (PX4095 (Grail) at 005 (New War on Cancer, Investor Presentation, July 2020)).
229. [REDACTED] } (PX8317 (Exact) at 004 [REDACTED] (*in camera*)).
230. Cancer treatment costs the United States \$150 billion annually. (PX4095 (Grail) at 005 (A New War on Cancer, Investor Presentation, July 2020)).

### B. CURRENT CANCER SCREENING METHODS

#### 1. Cancer Screening Methods Currently Exist for Only a Handful of Cancer Types

231. Single-cancer screening tests are used to identify five cancer types in the United States: breast, cervical, colon, lung, and prostate. (Bishop (Grail) Tr. 1374; Ofman (Grail) Tr. 3308; Abrams Tr. at 3729).
232. “Standard of care” screening methods refer to existing cancer screening methods approved and accepted in the medical field. (Lengauer (Third Rock Ventures) Tr. 168).
233. [REDACTED] (PX7040 (Getty (Guardant) IHT at 26-27); PX5027 (Illumina) at 018 [REDACTED] (*in camera*) ([REDACTED] })).

234. [REDACTED] } (Abrams Tr. at 3616-17; Conroy (Exact) Tr. 1736-37; PX7040 (Getty (Guardant) IHT at 26-27); PX5027 (Illumina) at 018 [REDACTED] (*in camera*); [REDACTED] })).
235. The USPSTF also recommends that clinicians offer prostate cancer screening, in the form of a prostate-specific antigen (PSA) test, to a limited set of patients. (RX3729, USPSTF, Final Recommendation Statement – Prostate Cancer: Screening, May 8, 2018 (<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/prostate-cancer-screening> (last visited July 16, 2021))).
236. The ACS also issues cancer screening guidelines in collaboration with cancer research experts for various cancers including breast, colorectal, lung, cervix, and prostate cancer. (Cance (American Cancer Society) Tr. 605-06).
237. Existing screening methods are highly effective at detecting these cancers in patients. (*See, e.g.*, PX2165 (Illumina) at 011 (Exact Sciences Q3 2020 Earnings Call, Oct. 27, 2020)).
238. [REDACTED] } (PX5024 (Illumina) at 022 (Board of Directors M&A Landscape Presentation, Apr. 28, 2020) (*in camera*)).
239. [REDACTED] } (PX5024 (Illumina) at 022 (Board of Directors M&A Landscape Presentation, Apr. 28, 2020) (*in camera*)).
240. Radiologic tests are used to screen for breast cancer and lung cancer. (Cance (American Cancer Society) Tr. 606).
241. Pap smears and examinations of the human papilloma virus DNA in blood screen for cervical cancer. (Cance (American Cancer Society) Tr. 606).
242. Examinations of prostate-specific antigen levels screen for prostate cancer. (Cance (American Cancer Society) Tr. 606).
243. Colonoscopy is the gold standard for colon cancer screening. (Conroy (Exact) Tr. 1547).
244. Exact’s Cologuard test has also been approved by the FDA as a screening test for colon cancer. (Conroy (Exact) Tr. 1547).
245. [REDACTED] } (Conroy (Exact) Tr. 1736-37; Nolan (Freenome) Tr. 2725; PX2009 (Illumina) at 017 (April BoD M&A Strategy Presentation, Apr. 28, 2020) (*in camera*); PX7040 (Getty (Guardant) IHT at 32)).

246. [REDACTED] } (PX5027 (Illumina) at 018 (in camera) ([REDACTED])); PX7040 (Getty (Guardant) IHT at 28 (65 percent compliance with colorectal screening recommendations))).

247. An Illumina Board document cites Grail for the proposition that [REDACTED] . (PX2009 (Illumina) at 017 (April BoD M&A Strategy Presentation, Apr. 28, 2020) (in camera)).

**2. Most Cancers Detected at Late Stages, Leading to Poor Outcomes**

248. The American Cancer Society’s Chief Medical and Scientific Officer, Dr. William Cance, testified that “[t]oday, there is no screening test available for all but five cancers, meaning that the vast majority of cancers are often diagnosed at very advanced stages of disease when treatment options are limited.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 6)).

249. The American Cancer Society describes cancer staging as follows: “Stage describes the extent or spread of cancer at the time of diagnosis.” (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019)).

250. Stages of cancer range from 0 to Stage IV. (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019)).

251. Stage 0 correlates with “in situ” cancer, which means that “cancer cells are present only in the layer of cells where they developed and have not spread.” (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019) (further explaining that “[i]f cancer cells have penetrated beyond the original layer of tissue, the cancer has become invasive and is categorized as local, regional, or distant based on the extent of the spread); RX3500 at 003 (Cancer Staging – National Cancer Institute, <https://www.cancer.gov/about-cancer/diagnosis-staging/staging> (last visited July 14, 2021) (“Stage 0 [means] [a]bnormal cells are present but have not spread to nearby tissue.”)).

252. Stage I cancer is “early” stage cancer and stage IV connotes “the most advanced disease.” (RX3030 at 011 (American Cancer Society, Cancer Facts & Figures 2019)).

253. From Stage 0 to Stage IV, “[t]he higher the number, the larger the cancer tumor and the more it has spread into nearby tissues[,]” until Stage IV, which means the “cancer has spread to distant parts of the body.” (RX3500 at 003 (Cancer Staging – National Cancer Institute, <https://www.cancer.gov/about-cancer/diagnosis-staging/staging> (last visited July 14, 2021)).

254. [REDACTED] (PX4172 (Grail) at 050 (Grail Board of Directors Meeting, Nov. 21, 2019) (in camera)).



255. By the time symptoms appear, cancer may already have grown and spread. (Conroy (Exact) Tr. 1736).

256. Most cancers are discovered after they have grown and spread in a person's body. (Nolan (Freenome) Tr. 2724-25).

257. A majority of cancers are discovered too late. (Conroy (Exact) Tr. 1736).

258. Over half of cancers in the United States are diagnosed at Stages III and IV. (PX2005 (Illumina) at 002 (ScreenCo – Early Cancer Detection on a Global Scale)).

259. [REDACTED]

[REDACTED]

{ }

(PX5027 (Illumina) at 019 [REDACTED] (in camera)).

260. [REDACTED]

(PX5024 (Illumina) at 022 ((Board of Directors M&A Landscape Presentation, Apr. 28, 2020) (in camera); PX8317 (Exact) at 020 [REDACTED] (in camera)).

261. Detection of cancer after it has progressed leads to high mortality rates. (PX2005 (Illumina) at 003 (ScreenCo - Early Cancer Detection on a Global Scale); Conroy (Exact) Tr. 1736 (explaining that by detecting cancer earlier, the odds of survival increase significantly)).

262. Patients that have cancer detected at an early stage by cancer screening tests benefit dramatically relative to patients that have cancer diagnosed at later stages. (Cance (American Cancer Society) Tr. 626).
263. Treatment and/or surgical costs are typically lower for cancers detected at earlier stages. (Conroy (Exact) Tr. 1736).
264. Dr. Cance described the benefits of screening early: “Screening for cancer increases the chances of detecting certain cancers early, when they might be easier to treat.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 5)).
265. [REDACTED] (PX8506 (Guardant) at 004 (in camera)).
266. [REDACTED] (PX8506 (Guardant) at 004 (in camera)).

**C. MCED TESTS ARE POISED TO REVOLUTIONIZE HOW CANCER IS DETECTED AND TREATED**

267. “[A]dvancements in blood-based cancer diagnostics present the possibility that some cancers previously undetectable until the late stages of disease could be detected at earlier stages, when treatment has higher likelihood of success.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 6)).
268. “We always dreamt that it would be great to detect cancer early, because early cancer detection saves lives. Even with the current treatments that we have, if you use the same treatment and you were tested back for cancer earlier, most individuals not only live longer but actually get cured.” (Lengauer (Third Rock Ventures) Tr. 273).
269. Guardant’s Nitin Sood testified how important MCED test development is: “cancer is a very serious disease, so it has a, you know, life altering impact on people. And we all know that with cancer, the sooner you detect it, the more localized it is, the more treatable it is and could mean the difference between life and death. And, therefore, the broader it’s available to the community as a large -- not only in the U.S. but globally, the greater benefit to the world.” (PX7090 (Sood (Guardant) Dep. at 111)).

**1. The Advantages of Liquid Biopsy**

270. “Traditionally, cancers are detected and diagnosed through a tissue biopsy or involve an invasive procedure like a colonoscopy.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 5)).
271. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (in camera)).

272. Liquid biopsy tests are a new type of cancer screening test being developed. (Cance (American Cancer Society) Tr. 608).
273. Prior to liquid biopsies, “in order to get information about a tumor, you were dependent on tissue samples of that tumor such that you could sequence it and then determine what was wrong in that particular individual’s genome.” (Getty (Guardant) Tr. 2489).
274. Dr. Cance of the American Cancer Society testified: “Liquid biopsy offers several advantages over tissue biopsy. Most patients are comfortable and familiar with blood draws. Whereas tissue biopsy requires the surgical removal of tumor tissue for common pathology testing, liquid biopsy extracts similar information from the patient’s blood.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 8)).
275. { [REDACTED] } (PX7053 (Fesko (Natera) IHT at 21); PX7068 (Perettie (FMI-Roche) IHT at 21-23) (*in camera*); Cance (American Cancer Society) Tr. 608-09; PX8398 (Cance (American Cancer Society) Decl. ¶ 8)).
276. In traditional tissue biopsies, a portion of tissue must be removed—sometimes surgically, which takes more time and is expensive. (PX7053 (Fesko (Natera) IHT at 21); PX7040 (Getty (Guardant) IHT at 51-54); PX8398 (Cance (American Cancer Society) Decl. ¶ 8)).
277. Liquid biopsy has a quicker turnaround time than a tissue biopsy and can be more accurate. (PX7040 (Getty (Guardant) IHT at 51-54); *see* PX4082 (Grail) at 012 (Email attaching Grail 2020 S-1/Amended, Sept. 2020) (noting that today patients are subjected to “potentially invasive and time-consuming workups” for “non-specific signs”). Natera’s Mr. Fesko testified that “there is a lot of heterogeneity within tumors, and so you may get a cleaner and more accurate signal from liquid biopsy than a tumor biopsy.” (PX7053 (Fesko (Natera) IHT at 21-22)).
278. “[L]iquid biopsy relies on blood, a regenerating and readily accessible sample. It can be difficult, and sometimes impractical, to obtain a tissue biopsy for some cancers. With liquid biopsy, however, the patient could readily give more blood for additional testing.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 8); *see also* PX2010 (Illumina) at 022 (TruSight Oncology 500 ctDNA: Sales Training) (“Up to 25% of cancer tissue needle biopsies yield insufficient material for clinical sequencing[.]”). { [REDACTED] } (PX7068 (Perettie (FMI-Roche) IHT at 22-23) (*in camera*)).
279. Natera’s Chief Business Officer, Jon Fesko, testified about the benefits of liquid biopsy: “The most obvious advantage is sometimes you cannot get tissue to test. In fact, I think in about a quarter of all lung cancer patients, there is no attainable tissue. So if you can use a liquid biopsy, you can guide a patient to the appropriate treatment without having access to -- you would not have access to that information otherwise.” (PX7053 (Fesko (Natera) IHT at 21); PX2010 (Illumina) at 022 (TruSight Oncology 500 ctDNA: Sales Training) (“Up to 25% of cancer tissue needle biopsies yield insufficient material for clinical sequencing[.]”)).

280. Liquid biopsy is generally safer and less uncomfortable for the patient than other current cancer screening tests. (PX8398 (Cance (American Cancer Society) Decl. ¶ 8); PX7040 (Getty (Guardant) IHT at 51-54); PX7042 (Gao (Singlera) IHT at 25-26); PX7044 (Stahl (Invitae) IHT at 45-46); PX0059 at 010-011 (Guardant 2020 10-K); PX8313 (Guardant) at 002 (Guardant 360 CDx Original PMA Application Attachment 6-1: Background Information on Liquid Biopsy for NGS Tests)).
281. Liquid biopsy tests are easier to repeat over time to observe changes than are tissue biopsy tests. (PX7040 (Getty (Guardant) IHT at 51-54)).
282. Patient compliance is also a recognized strength for liquid biopsy: “Where liquid biopsy has significant advantages over the current standard of care is simply around compliance most importantly.” (PX7040 (Getty (Guardant) IHT at 28)).
283. [REDACTED]
284. A liquid biopsy test begins with the collection of a blood (or other fluid) sample from the patient and is sent to the receiving laboratory. (PX4035 (Grail) at 016 (PiperJaffray, The 2015 Liquid Biopsy Report, Sep. 2015)).
285. Once at the laboratory, the test developer performs a “series of chemistry steps to isolate the DNA from” the patient’s blood and prepares it for sequencing in a process known as library preparation. (Bishop (Grail) Tr. 1379-81); *see also* Ofman (Grail) Tr. 3286; Chudova (Guardant) Tr. 1157-59; PX4035 (Grail) at 016 (PiperJaffray, The 2015 Liquid Biopsy Report, Sep. 2015); Rabinowitz (Natera) Tr. 306-09).
286. Following library preparation, the test sample is sequenced on a sequencing instrument to identify the order of base pairs in each molecule in the library. (PX0043 at 105-06 (Grail 2020 Form S-1); *see also* Berry (Illumina) Tr. 818-19 (explaining that Illumina sequencers’ primary analysis involves “base calling” by translating florescent signals to bases); Chudova (Guardant) Tr. 1159)).
287. [REDACTED] (Chudova (Guardant) Tr. 1159; PX7051 (Lengauer (Third Rock Ventures) IHT at 37) (*in camera*); PX7048 (Klausner (Grail) IHT at 119)).

**2. Analyte Molecules Present in Blood and Other Body Fluids**

a) Cell-Free DNA (cfDNA) and Circulating Tumor DNA (ctDNA)

288. Nearly all cells, including cancer cells, contain deoxyribonucleic acid (“DNA”). (PX0043 at 105 (Grail 2020 Form S-1)).

289. DNA is typically double stranded and is made up of complementary pairs of nucleotides, also known as base pairs. (PX0043 at 105 (Grail 2020 Form S-1)).
290. Each nucleotide in a DNA molecule contains one of four nitrogenous bases: Cytosine (C), Guanine (G), Adenosine (A), or Thymine (T). (Rabinowitz (Natera) Tr. 304).
291. DNA resides in the nucleus of most cells in the form of long (up to hundreds of millions of base pairs) molecules called chromosomes. (PX4035 (Grail) at 010 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015); PX0043 at 105 (Grail 2020 Form S-1)).
292. As cells within the body die, their chromosomes are broken down into small pieces and released into the blood stream as cell-free DNA (“cfDNA”). These cfDNA fragments are typically less than 200 base pairs long. (PX2010 (Illumina) at 008 (TruSight Oncology 500 ctDNA Sales Training); *see also* Chudova (Guardant) Tr. 1157-62; PX8313 (Guardant) at 002 (Guardant 360 CDx Original PMA Application Attachment 6-1: Background Information on Liquid Biopsy for NGS Tests)).
293. cfDNA is thus a harmless byproduct of cell death that is present in all human bloodstreams. (PX4035 (Grail) at 010-011 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015) (noting 50 to 70 million cells die every 24 hours)).
294. Cancerous cells go through the same process; when cancer cells die, their chromosomes are broken down into short fragments that are shed into the bloodstream as cfDNA. (PX2010 (Illumina) at 008 (TruSight Oncology 500 ctDNA Sales Training)).
295. The subset of cfDNA in the blood that originated from cancerous tumor cells is specifically called circulating tumor DNA (“ctDNA”). ctDNA reflects the genetic makeup of the tumor cells that released it and can differ from normal non-cancerous cfDNA in a variety of ways. (PX2010 (Illumina) at 009 (TruSight Oncology 500 ctDNA Sales Training); PX4035 (Grail) at 011-012 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015)).
296. “ctDNA is a direct measurement of cancer DNA, rather than an indirect measure of the effects of cancer.” (PX2005 (Illumina) at 005 (ScreenCo: Early Cancer Detection on a Global Scale, Presentation)).
297. Because “most of the DNA in blood is derived from normal cells[,]” there is a very small amount of ctDNA in blood relative to normal cfDNA. (Lengauer (Third Rock Ventures) Tr. 161-62).
298. [REDACTED] (PX2013 (Illumina) at 009 (Science & Technology Committee: Cancer Screening, Apr. 28, 2020) (*in camera*); PX7040 (Getty (Guardant) IHT at 39) (“you truly are finding a needle in a haystack”); PX7042 (Gao (Singlera) IHT at 39-40) (explaining that “the cancer signal [in the blood is] very subtle” at early stages); PX7045 (Chudova (Guardant) IHT at 30-31) (analogizing finding cancer signals to “find[ing] that needle in the haystack”).

299. The level of ctDNA in the blood can vary between individuals and tumor entities, but generally correlates to tumor size and stage, known as the “tumor burden.” (Chudova (Guardant) Tr. 1162-64).

300. [REDACTED]  
[REDACTED] PX7111 (Fesko (Natera) Dep. at 29) (*in camera*)).

301. Dr. Chudova, Guardant’s SVP of Technology, testified that “the challenges of detecting [ctDNA] become more significant as you go from late-stage disease to early-stage and then into screening.” (Chudova (Guardant) Tr. 1163).

b) Cell-Free RNA (cfRNA)

302. [REDACTED]  
[REDACTED] } (See Jamshidi (Grail) Tr. 4055-56 (*in camera*)).

303. Nearly all cells, including cancer cells, contain ribonucleic acid (“RNA”). (PX0043 at 105 (Grail 2020 Form S-1)).

304. [REDACTED]  
[REDACTED] (See Jamshidi (Grail) Tr. 4055-56 (*in camera*)).

305. [REDACTED] }  
(Bishop (Grail) Tr. 1481-82 (*in camera*)).

306. [REDACTED]  
[REDACTED] } (See, e.g., Nolan (Freenome) Tr. 2816 (*in camera*); Jamshidi (Grail) Tr. 4056 (*in camera*)) ([REDACTED]).

c) Proteins

307. [REDACTED] } (See Jamshidi (Grail) Tr. 4056-576 (*in camera*)).

308. [REDACTED]  
[REDACTED] (See, e.g., Jamshidi (Grail) Tr. 4055-56 (*in camera*)); Nolan (Freenome) Tr. 2711 (*in camera*)).

**3. Classes of Biomarkers Utilized for Cancer Detection**

309. “A biomarker is some form of signature or fingerprint” that may indicate the existence of cancer. (Lengauer (Third Rock Ventures) Tr. 160).

310. Mr. Conroy testified that a “biomarker is either a protein or DNA or RNA or other molecule in the body that is present when cancer is present and not present when cancer is not present.” (PX7058 (Conroy (Exact) IHT at 31-32)).

311. [REDACTED] } (See, e.g., Lengauer (Third Rock Ventures) Tr. 160, 175) (*in camera*); Aravanis (Illumina) Tr. 1880-81)).

312. Dr. Cance of the American Cancer Society explained that “[a]t this stage, it is unclear whether analyzing DNA mutations, DNA methylation patterns, chromosomal variants, RNA variations, protein markers, or some other method for detecting cancer in the blood will prove most effective.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 11).

a) DNA Mutations (Genomics)

313. Mutations are changes to the sequence of nucleotides in a DNA molecule. (Chudova (Guardant) Tr. 1166-67).

314. **There are multiple types of DNA mutations.** An example of a mutation would be a single nucleotide variant, where for example a C nucleotide changes to a T nucleotide. (Chudova (Guardant) Tr. 1166-67)).

315. A mutation that occurs in any cell in the body that is not a germ line cell is called a “somatic mutation.” (Chudova (Guardant) Tr. 1165.)

316. [REDACTED] } (PX7091 (Lengauer (Third Rock Ventures) IHT at 25) (*in camera*)).

317. Interrogating mutations in cfDNA falls within the larger field of study called “genomics.” (See, e.g., PX2369 (Illumina) at 014 (Email from J. Godsey, Illumina, to D. Baker et al., Illumina, Apr. 12, 2020, attaching “Recent Advances in Genomics-based Cancer Screening” draft, Apr. 28, 2020) ([REDACTED] ) (*in camera*)).

318. [REDACTED] (See, e.g., Chudova (Guardant) Tr. 1164-65; Lengauer (Third Rock Ventures) Tr. 175 (*in camera*); Nolan (Freenome) Tr. 2711 (*in camera*); PX7074 (Perettie (FMI-Roche) Dep. at 75) (*in camera*)).

b) DNA Methylation (Epigenomics)

319. Methylation is a process that plays a role in regulating gene expression, protein function, and RNA processing. (PX0043 at 106 (Grail 2020 Form S-1); see also Ofman (Grail) Tr. 3286 (stating that methylation refers to “little methyl groups that actually attach to the DNA” but do not change the DNA code); Rabinowitz (Natera) Tr. 357-58 (*in camera*) (explaining that [REDACTED] })).

320. “[A] methylated nucleotide undergoes a specific chemical modification that has a chemical mark added to that nucleotide that really changes how the cell functions.” For example, “we[] have the same DNA in our heart cells and our liver cells, generally, but [the] heart and liver function very differently. This is achieved partially by different methylation status of different genes, and so they can trigger a different development program or different expression program for the cells based on that chemical mark.” (Chudova (Guardant) Tr. 1167).
321. Each cell type in the body has a unique methylation pattern, known as its “fingerprint,” and modifications to such patterns can result in pronounced changes to cellular function. (PX0043 at 106 (Grail 2020 Form S-1)).
322. Methylation changes can lead to genes becoming over-expressed, under-expressed, or silenced altogether, thus resulting in excessive, reduced, or no protein production (respectively). (PX0043 at 106 (Grail 2020 Form S-1)). These deviations from normal cellular function can cause disease. For example, certain methylation modifications can turn off a tumor suppressor gene, leading to tumor growth and cancer. (PX0043 at 106 (Grail 2020 Form S-1)).
323. Abnormal methylation patterns are a hallmark of cancer, such as where unmethylated C in a nucleotide becomes a methylated C, or vice versa. (Chudova (Guardant) Tr. 1167; Ofman (Grail) Tr. 3286)).
324. [REDACTED] } (Chudova (Guardant) Tr. 1166 (“We call these modifications epigenetic changes or methylation changes.”); PX7068 (Perettie (FMI-Roche), IHT at 53-54) (*in camera*)).

c) DNA Fragmentation (Fragmentomics)

325. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 175 (*in camera*)).
326. [REDACTED] } (*See, e.g.,* Lengauer (Third Rock Ventures) Tr. 175 (*in camera*); Chudova (Guardant) Tr. 1243 (*in camera*)).

d) DNA Aneuploidy

327. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 1776 (*in camera*)).
328. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 36-37) (*in camera*); *see also* Lengauer (Third Rock Ventures) Tr. 175-76 (*in camera*)).



329. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 175-76 (*in camera*)).

e) RNA Expression (Transcriptomics)

330. [REDACTED] (See, e.g., PX7092 (Ofman (Grail) Dep. at 264) ([REDACTED] } (*in camera*); Nolan (Freenome) Tr. 2817 (explaining [REDACTED] } (*in camera*)).

331. [REDACTED] (See, e.g., Nolan (Freenome) Tr. 2711; Jamshidi (Grail) Tr. 4055-56 (*in camera*)).

f) Protein Levels (Proteomics)

332. Proteomics describes the analysis of proteins. (Nolan (Freenome) Tr. 2711).

333. [REDACTED] } (See, e.g., Lengauer (Third Rock Ventures) Tr. 175) (*in camera*)).

334. Interrogating protein expression levels falls within the field of study called “proteomics.” (Nolan (Freenome) Tr. 2711).

335. Proteomics platforms, which are separate from and “not direct replacements for” NGS platforms, are used to analyze proteins in patient samples. (deSouza (Illumina) Tr. 2325).

336. [REDACTED] } (See, e.g., Cance (American Cancer Society) Tr. 613; Nolan (Freenome) Tr. 2759 (*in camera*)).

337. [REDACTED] } (See, e.g., Cance (American Cancer Society) Tr. 613; Nolan (Freenome) Tr. 2759 (*in camera*)).

g) Multiomics

338. [REDACTED] (See Della Porta (Grail) Tr. 492 (*in camera*); Nolan (Freenome) Tr. 2710-11)).

339. [REDACTED] } (See, e.g., Cance (American Cancer Society) Tr. 613; Chudova (Guardant) Tr. 1166, 1243 (*in camera*); Nolan (Freenome) Tr. 2710-11 (describing Freenome’s multiomics platform as spanning genomics, transcriptomics, and proteomics)).

**4. MCED Tests Rely on Illumina NGS to Simultaneously Examine Thousands of Cancer Biomarkers in cfDNA**

340. [REDACTED]

341. [REDACTED]

(PX7102 (Gao (Singlera) Dep. at 131); PX7096 (Song (Omniome) Dep. at 141); PX7070 (Felton (Thermo Fisher) IHT at 26-28) (*in camera*); see PX7046 (George (Invitae) IHT at 74-75) (“Illumina emerged as the dominant player...about six years ago...”); PX7054 (Rabinowitz (Natera) IHT at 36, 41-42) (“[E]ven at that time [around 2010 and 2011] . . . Illumina was pretty dominant in the sequencing market.”); see also *infra* Section V.D. (Only Illumina NGS Platforms Meet the Requirements of MCED Tests)).

342. MCED tests examine blood samples to detect cancer at an early stage. (Cance (American Cancer Society) Tr. 609).

343. Dr. Cance explained in general terms how an MCED test works: “Many of these [MCED] tests examine fragments of DNA in the bloodstream and determine whether any DNA has been shed from cancer cells.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 7)).

344. [REDACTED] } (*See, e.g.,* Lengauer (Third Rock Ventures) Tr. 179-80 (*in camera*)).

345. MCED tests require the ability to detect on the order of one molecule of DNA in ten milliliters of blood. (*See, e.g.,* Lengauer (Third Rock Ventures) Tr. 162-63). NGS can detect one molecule of DNA in ten milliliters of blood. (Lengauer (Singular Genomics) Tr. 162-63).

346. As Jay Flatley, former Illumina CEO, told Illumina investors in a 2016 investor call:

To reliably detect ctDNA across cancer types with the needed sensitivity and specificity requires ultra-deep sequencing, thousands or more times the depth and breadth that has been used routinely in a [sic] clinical settings to date. . . .

We expect the clinical trials required to show statistical significance could require sequencing between 100K and 300K genomes at 60X depth, or the equivalent of two whole genomes per sample, implying a project that could be as large as 6 times the scope of Genomics England. Only Illumina can sequence at the price points necessary to enable the required trials, . . .

(PX0037 at 004-005 (Illumina, Grail Investor Call Script, Jan. 10, 2016)).

347. NGS technology allows for the detection of a broad range of DNA mutations within a blood sample, which in turn allows for the analysis of many mutations associates with cancer. (PX8313 (Guardant) at 002 (Background Information on Liquid Biopsy for NGS Tests)).
348. Unlike other testing technologies, NGS can simultaneously screen for thousands of biomarkers (such as mutations or methylation patterns) that potentially signal cancer within the body. (PX7042 (Gao (Singlera) IHT at 38-40)).

**5. Illumina and Grail Were Not the First to Discover the Use of cfDNA for Cancer Screening Technology**

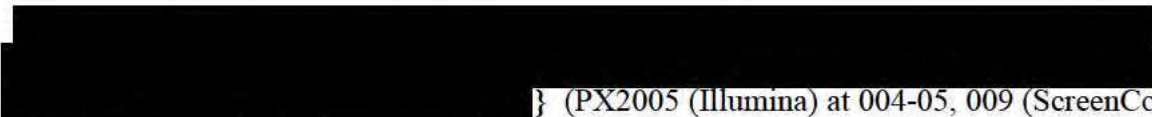
349. A May 2017 Grail board presentation stated that Dr. Dennis Lo is the Director of the “[l]aboratory at forefront of cfDNA in NIPT & cancer since 1997.” (PX4620 (Grail) at 007 (Grail, Project Knight – Board Update II, May 10, 2017)).
350. Singlera Genomics co-founder and scientific advisor, Dr. Gary Gao, began collaborating with Dr. Dennis Lo of the Chinese University of Hong Kong on noninvasive prenatal testing (“NIPT”) research in 2007. (Gao (Singlera) Tr. 2863-64; 2867-68).
351. A noninvasive prenatal test (“NIPT”) is a blood-based test performed on expectant mothers designed to determine whether the fetus has chromosomal abnormalities, including Down syndrome. (Qadan (Illumina) Tr. 4121).
352. [REDACTED] (PX7113 (Rabinowitz (Natera) Dep. at 36) (*in camera*)).
353. Together, Dr. Gao, Singlera’s Co-Founder and current Scientific Advisor, and Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, developed a protocol for sequencing cfDNA in blood samples of pregnant women to identify the presence of fetal chromosome 21 trisomy (down syndrome). (Gao (Singlera) Tr. 2863-64; 2867-68).
354. Dr. Gao, Singlera’s Co-Founder and current Scientific Advisor, and Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, published a paper in the Proceedings of National Academy of Science journal in 2008 presenting the results of their research on the detection of fetus chromosome trisomy using cfDNA. (Gao (Singlera) Tr. 2863-64; 2867-68). Dr. Gao used the research from his 2008 paper with Dr. Dennis Lo, a professor at the Chinese University of Hong Kong, to begin research on the use of cfDNA for cancer screening. (Gao (Singlera) Tr. 2863-65; 2867-68).
355. Dr. Gao published a paper on DNA methylation for use in applications such as cancer detection in 2009 with Singlera co-founder Professor Kun Zhang of the University of California San Diego. (Gao (Singlera) Tr. 2863-65).
356. Dr. Gao testified at trial that he was not aware of efforts by Grail to develop cancer screening technology when he began his research related to cancer detection. (Gao

- (Singlera) Tr. 2869). Dr. Gao further testified that Singlera was “way ahead of Grail” in its efforts to develop a cancer screening technology. (Gao (Singlera) Tr. 2869).
357. Dr. Dave Ahlquist, a gastroenterologist at Mayo Clinic, conducted research for years looking for biomarkers that could provide early detection of colon cancer. (Conroy (Exact) Tr. 1538-39).
358. In March 2009, Dr. Ahlquist told Mr. Conroy of his vision for detecting many or most cancers from a simple blood draw. (Conroy (Exact) Tr. 1539). Dr. Ahlquist called this vision a “pan-cancer” test, which would look for tiny fragments of cancer DNA in a patient’s blood. (Conroy (Exact) Tr. 1539-40).
359. Dr. Ahlquist’s vision for a pan-cancer test was the genesis of Exact’s mission to detect cancer earlier. (Conroy (Exact) Tr. 1540-41).
360. Exact and Mayo Clinic entered into a research and development partnership in June 2009 that has continued for 12 years. (Conroy (Exact) Tr. 1536-37). Dr. Ahlquist participated in the Exact-Mayo Clinic partnership. (Conroy (Exact) Tr. 1536-37; 1539-40).
361. Dr. Bert Vogelstein’s lab at Johns Hopkins University “published the first description of cancer genomes, what we called cancer genome landscapes” in approximately 2009 or 2010. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 61)).
362. Alongside teams of researchers, Dr. Vogelstein helped discover that “a relatively small number of genes play[ ] a major role in most human cancer types.” (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 2)).
363. Dr. Vogelstein and the group of researchers with whom he works was awarded the international prize from the American Association of Cancer Research for “pioneering the development of liquid biopsies.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 78-79)).
364. CancerSEEK was developed by Dr. Bert Vogelstein within his lab at Johns Hopkins University. (Conroy (Exact) Tr. 1542-43).
365. Dr. Vogelstein ran clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer. (Conroy (Exact) Tr. 1542-43).
366. Dr. Vogelstein is a co-founder of Thrive Earlier Detection Corp. (“Thrive”). (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 27)). Dr. Vogelstein’s CancerSEEK became part of Thrive. (Conroy (Exact) Tr. 1542-43).
367. The original version of CancerSEEK underwent its first study about three to four years ago. (Conroy (Exact) Tr. 1545-46).
368. Using methods similar to those used in NIPT, Dr. Lo developed a method for detecting cancer signals in circulating cfDNA. (PX2858 (Illumina) at 001 (Email from R. Bookstein, Illumina, to N. Naclerio, Illumina, Aug. 9, 2012)).

369. In August 2012, Illumina’s Director of Corporate and Venture Development, Robert Bookstein, wrote to Illumina’s SVP of Corporate and Venture Development, Nicholas Naclerio, to alert Mr. Naclerio of research by Dr. Dennis Lo. (PX2858 (Illumina) at 001 (Email from R. Bookstein, Illumina, to N. Naclerio, Illumina, Aug. 9, 2012)).
370. Mr. Bookstein wrote to Dr. Naclerio that, because Dr. Lo’s method of detecting cancer through cfDNA “requires huge numbers . . . of random genomic reads, it’s a perfect application for [Illumina’s] largest-capacity instruments.” (PX2858 (Illumina) at 001 (Email from R. Bookstein, Illumina, to N. Naclerio, Illumina, Aug. 9, 2012)).
371. Mr. Bookstein wrote to Dr. Naclerio that he thought that Dr. Lo’s method of detecting cancer through cfDNA “could be built into a business rivaling or exceeding [noninvasive prenatal testing].” (PX2858 (Illumina) at 001 (Email from R. Bookstein, Illumina, to N. Naclerio, Illumina, Aug. 9, 2012)).
372. Mr. Bookstein suggested to Dr. Naclerio that Illumina “scoop up [Dr. Lo’s] entire IP portfolio and build it inside Illumina.” (PX2858 (Illumina) at 001 (Email from R. Bookstein, Illumina, to N. Naclerio, Illumina, Aug. 9, 2012)).
373. On September 3, 2012, Illumina held a call with Dr. Dennis Lo relating to his discovery that cancer signals could be detected through cfDNA and sought next to review Dr. Lo’s “filed patent applications.” (PX2859 (Illumina) at 001-002 (Email from R. Bookstein, Illumina, to P. Fromen, Illumina, et al., Sept. 5, 2012)). In notes from the call, Illumina’s attendees wrote the question, “How will a clinician use this type of data?” (PX2859 (Illumina) at 004 (Email from R. Bookstein, Illumina, to P. Fromen, Illumina, et al., attaching notes “Dennis Lo’s talk 9/03/12,” Sept. 5, 2012)). Responses to the question included “Blood biopsy – non-invasive screening” and “Potential for detecting cancer prior to actual detection of a primary tumor.” (PX2859 (Illumina) at 004 (Email from R. Bookstein, Illumina, to P. Fromen, Illumina, et al., attaching notes “Dennis Lo’s talk 9/03/12,” Sept. 5, 2012)).
374. It was not until “a little before 2015” that Illumina began work related to Grail and then created Grail as a corporate entity in 2016. (deSouza (Illumina) Tr. 2195-96).

**6. MCED Test Background**

a) MCED Tests Seek to Detect Multiple Cancers Simultaneously in Asymptomatic Individuals

375. As discussed in detail below in Section III., MCED tests screen for multiple cancers in an asymptomatic population and all use Illumina’s NGS platforms.
376.  (PX2005 (Illumina) at 004-05, 009 (ScreenCo – Early Cancer Detection on a Global Scale Presentation, 2015); see also PX5027 (Illumina) at 016-17 (Board of Directors Meeting, Aug. 4, 2020) (in camera)).

377. [REDACTED] } (See, e.g., PX0086 at 001 (Grail Press Release: GRAIL Presents Interventional PATHFINDER Study Data at 2021 ASCO Annual Meeting and Introduces Galleri, a Groundbreaking Multi-Cancer Early Detection Blood Test, June 4, 2021) (describing Galleri as a “multi-cancer early detection (MCED) blood test”); PX8314 (Guardant) (Multi-Cancer Screening, Dec. 2020) (*in camera*); PX8324 (Roche) at 003 [REDACTED] (*in camera*); PX8392 (Exact) at 002 (Pipeline Review, Jan. 2021) (*in camera*)).

378. [REDACTED] } (See, e.g., PX4082 (Grail) at 008-009 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*); PX7100 (Chudova (Guardant) Dep. at 15-16); PX7094 (Nolan (Freenome) Dep. at 252-53) (*in camera*); PX4116 (Grail) at 013 (Email from M. Podoll, Morgan Stanley, to A. Freidin, Grail, et al., attaching IPO Roadshow Video Outline: Project Galileo, Aug. 2020)).

379. An Illumina Board presentation analyzing the potential acquisition of Grail notes that [REDACTED] (PX5027 (Illumina) at 005 [REDACTED] (*in camera*)).

380. [REDACTED] (PX5027 (Illumina) at 005 [REDACTED] (*in camera*)).

381. [REDACTED] (PX7040 (Getty (Guardant) IHT at 29-32); see also PX4082 (Grail) at 008-009 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*); PX7100 (Chudova (Guardant) Dep. at 15-16); PX7094 (Nolan (Freenome) Dep. at 252-53) (*in camera*)).

382. Because MCED tests are targeted towards patients who do not have symptoms of, and have not been treated for, cancer, [REDACTED] (See, e.g., PX7058 (Conroy (Exact) IHT at 103-04) (*in camera*); PX7040 (Getty (Guardant) IHT at 29-32)).

383. Singlera’s Dr. Gao explained that sensitivity of a cancer screening test indicates “a true positive, so when the person has a disease, your test tells positive results.” (PX7042 (Gao (Singlera) IHT at 32)).

384. In describing what the specificity of an MCED test means, Singlera’s Gao explained that, for example, when a test subject “does not have cancer, [they] have negative test results.” (PX7042 (Gao (Singlera) IHT at 31)).

385. Christoph Lengauer, former Chief Officer and Co-Founder of Thrive, testified that, as an example to describe sensitivity, if you have ten individuals with cancer and your test identifies three of those individual as having cancer, the sensitivity of that test would be 30 percent. So seven individuals would be false-negatives. (Lengauer (Third Rock Ventures) Tr. 245). (Lengauer (Third Rock Ventures) Tr. 245).

386. In explaining the importance of high sensitivity (i.e., minimizing false negatives) to cancer screening tests, Guardant’s Chudova testified:

Any patient that you miss as a result of that screening will continue to develop their cancer in an asymptomatic, potentially, state and not be diagnosed until either they become symptomatic or they will be diagnosed with another modality, and so any missed patients in the context of screening will continue on to develop the disease without awareness that at early stage could have been helpful in preventing more advanced disease.

(PX7045 (Chudova (Guardant) IHT at 63-64)).

387. Guardant’s Chudova explained the consequences of a false positive cancer screening test result:

[T]he physician would need to follow up with all sorts of radiological and other interventions to try to localize the cancer that the test is suggesting they have, whereas in fact they don’t, and so the risk is exposure to a lot of subsequent diagnostic procedures that would have been totally unnecessary because the result is a false positive result.

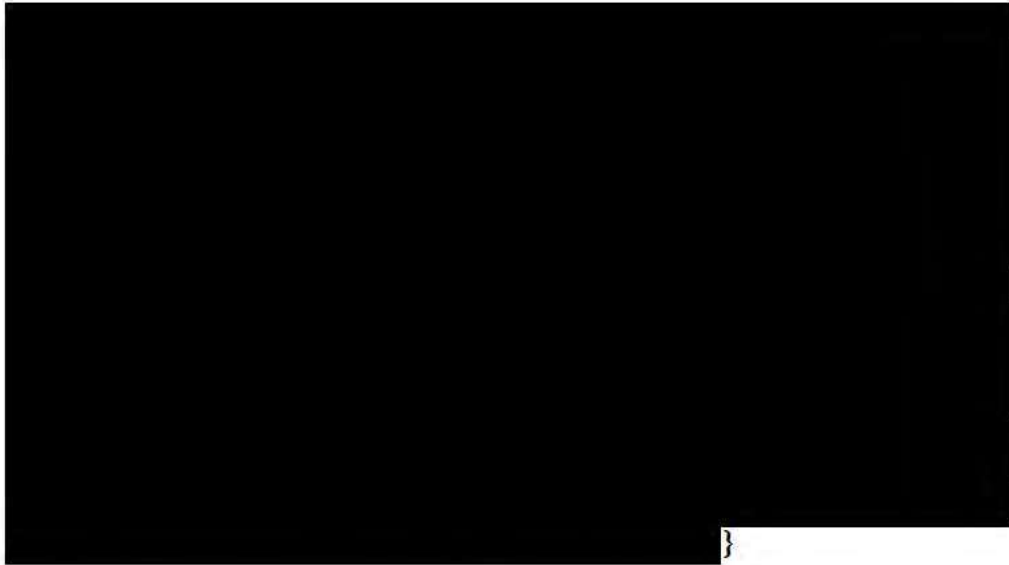
(PX7045 (Chudova (Guardant) IHT at 64)).

388. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 95-96) (*in camera*)).

389. [REDACTED] (PX7058 (Conroy (Exact) IHT at 93) (*in camera*)).

390. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 96) (*in camera*)).

391. [REDACTED]



(PX7058 (Conroy (Exact) IHT at 96-97 (*in camera*)).

392. Guardant’s Getty explained that a false positive screening test could harm a “patient mentally” and also trigger “very invasive” follow-up procedures. (PX7040 (Getty (Guardant) IHT at 36-37)).

393.  } (PX7055 (Otte (Freenome) IHT at 84) (*in camera*)).

394. Singlera’s Gao indicated that a false positive test result is a “potentially damaging, worrisome thing.” (PX7042 (Gao (Singlera) IHT at 31)).

395. In discussing the importance of high sensitivity and specificity of cancer screening tests, Singlera’s Gao explained that MCED test providers “don’t want to miss any disease diagnosis. . . . You don’t [want to] have any false negative [results]. . . . When[, for example, an individual] has a gastric cancer, your test” must really be able to detect the presence of gastric cancer. (PX7042 (Gao (Singlera) IHT at 32)).

396. Grail’s former CEO, Hans Bishop, testified that “[i]t’s very important” to have a low false positive rate for a cancer screening test. (Bishop (Grail) Tr. 1385-86).

397. Grail’s former CEO, Hans Bishop, testified that “the lower the false positive rate, the lower the unnecessary stress, the lower the risk of investigational harms, and the lower the wasted money on unnecessary work-ups” following a false diagnosis. (Bishop (Grail) Tr. 1385-86).





407. [REDACTED] } (Aravanis (Illumina) Tr. at 1802-1804 (*in camera*) (referencing PX4075)).

(1) Grail

408. Grail’s Galleri test aims to detect cancer signals by identifying abnormal methylation patterns in a patient’s DNA. (Bishop (Grail) Tr. 1319-20; 1373).

409. Galleri identifies regions of a patient’s DNA that are hypermethylated or hypomethylated. (Bishop (Grail) Tr. 1320). Galleri seeks to differentiate hyper- or hypomethylation patterns from those in healthy patients. (Bishop (Grail) Tr. 1320).

410. At trial, Dr. Ofman described Galleri’s analysis of DNA methylation: “Grail’s test looks at over a million of these methylation sites in over a hundred thousand regions of the genome.” (Ofman (Grail) Tr. 3287).

411. [REDACTED] } (Jamshidi Tr. 4055-56 (*in camera*); *see also* Bishop (Grail) Tr. 1481-82 (*in camera*)) [REDACTED] }; PX4082 (Grail) at 014 (Grail Amended S-1) (“We seek to continually enhance the performance and features of our tests, including seeking ways to improve sensitivity and reduce sequencing costs”).

412. Grail’s Dr. Jamshidi [REDACTED] (PX7103 (Jamshidi (Grail) Dep. at 87-88) (*in camera*)).

413. [REDACTED] } (PX4250 (Grail) at 012 (Grail, [REDACTED] } (*in camera*)). [REDACTED] See (PX4054 (Grail) at 004 [REDACTED] (*in camera*)).

(2) Thrive/Exact

414. Dr. Lengauer testified that [REDACTED]

- [REDACTED] (Lengauer (Third Rock Ventures) Tr. 194 (*in camera*)).
415. Exact/Thrive's CancerSEEK test combines NGS-based DNA mutation detection technology and protein detection technology. (Conroy (Exact) Tr. 1544).
416. [REDACTED] } (PX8572 (Exact) at 046 (Exact Sciences, Innovation & Technology Committee Spring Meeting Presentation, April 16, 2021) (*in camera*)).
417. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 188 (*in camera*); *see also* Bishop (Grail) Tr. 1496 (*in camera*)).
418. [REDACTED] (Della Porta (Grail) Tr. 483) (*in camera*)).
419. [REDACTED]
- (3) [REDACTED]
420. [REDACTED] } (*in camera*)).
421. [REDACTED]
422. [REDACTED]
423. [REDACTED]
424. [REDACTED]
425. [REDACTED]

(4) Guardant

426. [REDACTED] } (Getty, Tr. 2495-96; PX7045 (Chudova (Guardant) IHT at 98, 101-102) (*in camera*)).
427. Guardant is developing methylation-based technology to augment its existing somatic mutation technology. (Chudova (Guardant) Tr. 1165-66).
428. Guardant’s therapy selection tests and minimal residual test for colorectal cancer look for mutations. (Chudova (Guardant) Tr. 1148-52; 1164-65).
429. Dr. Chudova, SVP of Technology for Guardant, explained that Guardant’s technology “look[s] for nucleotide changes that are distinct between fragments of interest and [the] majority of the fragments in the body and that . . . links it to the tumor origin.” (Chudova (Guardant) Tr. 1165).
430. Guardant is working on extending its minimal residual disease technology platform into an MCED testing platform to detect “a majority of the known cancers.” (Chudova (Guardant) Tr. 1152-53).
431. Dr. Chudova testified that cancer screening “requires higher sensitivity of the assay, because there’s fewer [ctDNA] fragments, and you cannot rely exclusively on somatic mutations to identify presence of tumor.” (Chudova (Guardant) Tr. 1165).
432. Because of the higher sensitivity required for MCED screening, Guardant has “significantly augmented” its somatic mutation technology with methylation as a second, distinct type of cancer biomarker. (Chudova (Guardant) Tr. 1165-66).
433. [REDACTED] } (Chudova (Guardant) Tr. at 1243 (*in camera*)).
434. [REDACTED] } (Getty, Tr. 2625 (*in camera*)).
435. [REDACTED] } (Getty, Tr. 2628 (*in camera*)).
436. [REDACTED] (Della Porta (Grail) Tr. 482 (*in camera*)).
437. [REDACTED] } (PX4145 (Grail) at 009 (Grail, “An Overview,” Aug. 14, 2019) (*in camera*)).

438. [REDACTED]

(5) Freenome

439. Freenome’s CEO, Mike Nolan, testified that Freenome is “starting with detection of colorectal cancer and advanced adenomas from a blood sample and then taking a stepwise approach to get to other cancer types so that we can deliver benefits of early detection across a range of different cancers.” (Nolan (Freenome) Tr. 2706).

440. Freenome’s Nolan further testified that Freenome currently has “a multicancer program” and has prospectively collected samples “for the purpose of product development, across a range of cancer types.” (Nolan (Freenome) Tr. 2709).

441. [REDACTED] (PX7121 (Otte (Freenome) Dep. at 105) (*in camera*); see also Nolan (Freenome) Tr. 2711 (stating that Freenome’s multiomics platform analyzes [REDACTED])).

442. [REDACTED] (PX7121 (Otte (Freenome) Dep. at 56) (*in camera*)).

443. [REDACTED] (Nolan (Freenome) Tr. 2748 (*in camera*)).

444. [REDACTED] (Della Porta (Grail) Tr. 483 (*in camera*)).

445. [REDACTED] (PX4145 (Grail) at 009 (Grail, “An Overview,” Aug. 14, 2019) (*in camera*)).

446. [REDACTED]

(6) Singlera

447. Dr. Gao testified that Singlera’s “goal is to detect cancer early, all kinds of cancer. (PX7042 (Gao, IHT at 21, 118-19)).

448. Singlera’s PanSeer test is designed to detect “all kinds of cancer” using a blood-based approach. (Gao (Singlera) Tr. 2873).

449. Singlera’s PanSeer test analyzes cfDNA using methylation patterns as biomarkers to detect cancer. (Gao (Singlera) Tr. 2875; PX7042 (Gao (Singlera) IHT at 21)).

450. Singlera published a paper in Nature Communications in 2020 demonstrating the performance of its platform for five different cancers in terms of sensitivity and specificity. (Gao (Singlera) Tr. 2875).

451. [REDACTED] (Della Porta (Grail) Tr. 483 *in camera*).

452. [REDACTED] } (PX4145 (Grail) at 009 (Grail, "An Overview," Aug. 14, 2019) *in camera*).

453. [REDACTED]

(7) Helio

454. Helio is "a company in the space of early cancer detection using blood as the specimen trying to determine initially the early detection of liver cancer but with ambitions to do additional cancers, including ultimately a multicancer test." (Chahine (Helio) Tr. 1000).

455. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 15)).

456. [REDACTED] } (PX7077 (Chahine (Helio) Dep. at 16) *in camera*).

457. [REDACTED] } (Chahine (Helio) Tr. 1000-01; PX7077 (Chahine (Helio) Dep. at 16) *in camera*).

458. [REDACTED] (Della Porta (Grail) Tr. 483-84 *in camera*).

459. [REDACTED] (PX4145 (Grail) at 009 (Grail, "An Overview," Aug. 14, 2019) *in camera*).

460. [REDACTED]

(8) [REDACTED]

461. [REDACTED]

462. [REDACTED]

463. [REDACTED]

464.

[REDACTED]

465.

[REDACTED]

c) MCED Tests Are Designed to Complement Existing Screening Methods

466.

[REDACTED] (PX7040 (Getty (Guardant) IHT at 154-155); PX7051 (Lengauer (Third Rock Ventures) IHT at 176) (*in camera*); PX7083 (Bishop (Grail) Dep. at 24-25)).

467.

[REDACTED] (Conroy (Exact) Tr. 1647 (*in camera*)).

468.

Dr. Cance anticipates that MCED tests will be part of annual physicals for certain individuals: “I expect that, once available, these tests might be used as part of patients’ annual primary (wellness) care. For example, any individual above the age of 50 could receive a multi-cancer early detection test at their annual physical through their primary physician.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 9)).

469.

Dr. Cance declared that MCED tests will complement existing screening methods: “Until they are fully validated and studied, multi-cancer early detection tests may complement but not replace the existing screening methods.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 9)).

470.

Dr. Cance described the potential to use MCED tests as a preliminary screening tool: “These multi-cancer early detection tests could ultimately be used as a preliminary screening test to determine whether further cancer-specific screening, such as a colonoscopy or other more invasive diagnostic methods, is needed.” (PX8398 (Cance (American Cancer Society) Decl. ¶ 9)).

471.

Mr. Bishop testified on the distinction between single cancer and MCED tests:  
  
[T]he reason we should not use Galleri instead of any of those single tests is because those single tests are optimized for detecting those single cancers. They have a higher detection rate than we do for those individual cancers. And the clinical goal here is to maximize the number of cancers we detect early. And we do that by using Galleri in conjunction with single-cancer screening tests.

(Bishop (Grail) Tr. 1390-91).

472. Mr. Bishop explained that, in comparison to the existing standard of care screening tests, Galleri is not as sensitive:

[W]ithout exception, the single-cancer tests used today for prostate, cervix, breast and colon -- and I can list the particular tests that are regarded as standard of care today -- their detection rate for those single cancers at their specificity is higher than the detection rate for those individual single cancers that the Galleri test has. That's the essential reason why these tests should be used alongside each other.

(Bishop (Grail) Tr. 1392).

473. [REDACTED] } (Della Porta (Grail) Tr. 544 (*in camera*)).

474. [REDACTED]  
(PX7058 (Conroy (Exact) IHT at 119-120) (*in camera*)).

475. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 112-13) (*in camera*)).

**D. THE U.S. MCED TEST MARKET IS EXPECTED TO REACH TENS OF BILLIONS OF DOLLARS ANNUALLY IN REVENUES**

**1. Illumina Expects Cancer Screening to Be “Probably the Single Biggest Market Segment That We Can Imagine”**

476. In 2016, Jay Flatley, then the Chairman and Chief Executive Officer of Illumina, told investors that cancer screening is a “gigantic opportunity” and “probably the single biggest market segment that we can imagine.” (PX0045 at 023 (Illumina, Illumina Q1 2016 Results Earnings Call Transcript, May 4, 2016)).

477. “Illumina has recognized that cancer screening is [REDACTED] [REDACTED] } with a projected market size of tens of billions of dollars by 2035. . . .” (Answers and Defenses of Respondents Illumina and Grail at 018 (¶ 10) (*in camera*)).

478. Driving its proposed acquisition of Grail was Illumina’s recognition that, [REDACTED] [REDACTED] } (See PX2465 (Illumina) at 006-008 [REDACTED] (*in camera*); PX2488 (Illumina) at 007-009 [REDACTED] (*in camera*)).



479. [REDACTED] . (PX2035 (Illumina) at 002 (Illumina, Oncology Testing 5-Year Strategy Refresh, 2020) (*in camera*)).

480. [REDACTED] (PX2488 (Illumina) at 003 [REDACTED] (*in camera*)).

481. [REDACTED] } (PX2488 (Illumina) at 003, 007 [REDACTED] (*in camera*)).

482. [REDACTED] (PX2316 (Illumina) at 023 (Email from J. Goswami, Illumina, to A. Qadan, Illumina, et al., Apr. 29, 2020, attaching presentation entitled “Board of Directors M&A Landscape”) (*in camera*)).

483. In presentations to Illumina’s board of directors, Illumina executives warned, [REDACTED] } (PX2488 (Illumina) at 009 [REDACTED] (*in camera*); see also PX2465 (Illumina) at 008 [REDACTED] (*in camera*)).

484. [REDACTED] } (PX2488 (Illumina) at 009 [REDACTED] (*in camera*); see also PX2465 (Illumina) at 008 [REDACTED] (*in camera*); PX2169 (Illumina) at 043 [REDACTED]



{ }

**2. Other MCED Developers Also Project Tens of Billions of Dollars in Revenues for the MCED Test Market**

485. [REDACTED] } (PX8324 (Roche) at 012 [REDACTED] (*in camera*)).

486. Guardant Senior Vice President of Commercial, Bill Getty, testified that Guardant estimates the multi-cancer early detection testing market will exceed \$50 billion in revenue. (Getty (Guardant) Tr. 2503; PX7105 (Getty (Guardant) Dep. at 50-51)).

487. As Guardant’s Getty explained, “[t]he sequencing business is a much, much smaller slice . . . relative to that 60-billion-dollar [blood-based cancer screening business] opportunity. So as an organization, [Illumina’s] acquisition of Grail is ostensibly geared to moving into this much bigger opportunity and maximizing that opportunity.” (PX7105 (Getty (Guardant) Dep. at 68)).

488. [REDACTED] } (Berry (Illumina) Tr. 767-768) (*in camera*)).

489. [REDACTED] (RX0894 (Helio) at 10 (Helio, Helio Health) (*in camera*)).

490. Freenome’s Mr. Nolan testified that the MCED market “is huge and the unmet need is huge.” (Nolan (Freenome) Tr. 2727).
491. Cowen—a financial services firm—identified multi-cancer screening tests for asymptomatic patients as its own market and assessed that it would have approximately a \$5 to \$50 billion target addressable market in its report on liquid biopsy. (PX2752 (Illumina) at 007 (Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sept. 18, 2020)). Cowen’s market assessment noted that single cancer tests, tests targeting high risk patients, and tests with a non-screening function as separate market opportunities. (PX2752 (Illumina) at 007 (Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sept. 18, 2020)).

**E. REGULATORY APPROVAL PROCESS AND REIMBURSEMENT FRAMEWORK FOR MCED TESTS**

492. [REDACTED] (Bishop (Grail) Tr. 1331-33; Della Porta (Grail) Tr. 456-58; Ofman (Grail) Tr. 3371-72 (*in camera*)).
493. Grail has begun entering into contracts with some health systems and self-employed customers for the Galleri test, but, according to Grail Chief Medical Officer Josh Ofman, Grail does not expect to receive widespread payer coverage until after obtaining premarket approval (“PMA”) from the FDA. (See PX7092 (Ofman (Grail) Dep. at 175-176)).

**1. Laboratory Developed Tests (LDTs)**

494. A laboratory-developed test (“LDT”) is a test developed on-site at a single clinical laboratory, which uses components from multiple suppliers to put together a specific test that is then validated in that laboratory. (Febbo (Illumina) Tr. 4320; *see also* PX0043 at 041 (Grail 2020 Form S-1) (“LDTs are in vitro diagnostic tests that are intended for clinical use and are designed, manufactured, and used within a single laboratory”)).
495. [REDACTED] } (Goswami (Illumina) Tr. 3185-86; *see also* Rabinowitz (Natera) Tr. 382 (*in camera*)).
496. LDTs, in order to be offered to patients, must be performed in labs that have CLIA certification. (Febbo (Illumina) Tr. 4320).
497. The Centers for Medicare & Medicaid Services (“CMS”) certifies CLIA compliance of the laboratories themselves. (Ofman (Grail) Tr. 3317-18).
498. [REDACTED] } (PX7111 (Fesko (Natera) Dep. at 181 (*in camera*))); *see also* Goswami (Illumina) Tr. 3186 (stating that the test developer “takes all responsibility for

- certifying the test and validating it”); PX7097 (Felton (Thermo Fisher) Dep. at 51) (stating that an LDT test itself is “self-validated” under CLIA/CAP regulation in the U.S.)).
499. CLIA/CAP guidelines for LDTs are not overseen by the FDA. (Goswami (Illumina) Tr. 3221-22, 3262; *see also* PX4035 (Grail) at 038 (PiperJaffray, The 2015 Liquid Biopsy Report, Sept. 2015) (stating that LDTs are exempt from FDA’s oversight but laboratories with LDTs must follow CLIA)).
500. The FDA does not review or validate safety or efficacy data associated with a test sold as an LDT. (Goswami (Illumina) Tr. 3262; *see also* PX0043 at 041 (Grail 2020 Form S-1) (stating that “[a]lthough LDTs are classified as medical devices and FDA has statutory authority to ensure that medical devices are safe and effective for their intended uses, FDA has historically exercised enforcement discretion and has not enforced certain applicable FDA requirements, including premarket review, with respect to LDTs”)).
501. [REDACTED]  
 [REDACTED] (See PX7111 (Fesko (Natera) Dep. at 171) (*in camera*)).
502. [REDACTED] } (See PX7051 (Lengauer (Third Rock Ventures) IHT at 146-147) (*in camera*); PX7058 (Conroy (Exact) IHT at 142) (*in camera*)).
503. Grail’s Galleri test is an LDT. (Ofman (Grail) Tr. 3317; Goswami (Illumina) Tr. 3222).
504. As an LDT, Grail’s Galleri test does not currently require FDA approval or oversight to be sold. (Goswami (Illumina) Tr. 3222).
505. [REDACTED] } (PX7050 (Nolan (Freenome) IHT at 279-280) (*in camera*); *see also* PX7051 (Lengauer (Third Rock Ventures) IHT at 149) (*in camera*)).

**2. FDA Approval Process**

506. [REDACTED] } (PX7092 (Ofman (Grail) Dep. at 175-176); PX0043 at 115, 132 (Grail 2020 Form S-1); PX7058 (Conroy (Exact) IHT at 87-88) (*in camera*)).
507. [REDACTED] } (See PX7055 (Otte (Freenome) IHT at 32-33) (*in camera*); PX7068 (Perettie (FMI-Roche) IHT at 33) (*in camera*)).
508. Grail CEO Hans Bishop testified at trial that FDA approval is “very necessary for getting American citizens access to our test.” (Bishop (Grail) Tr. 1368).

509. Illumina, Grail, and MCED test developer witnesses, ordinary course documents, and external industry researchers state that FDA approval is a necessary input to achieve Medicare coverage of MCED testing from CMS. (deSouza (Illumina) Tr. 2414); Ofman (Grail) Tr. 3319-20; Conroy (Exact) Tr. 1734; Chahine (Helio) Tr. 1029 (explaining that CMS issued guidance “stating that it would require FDA approval for reimbursement under CMS” for early cancer detection); PX4172 (Grail) at 059 (Grail Board of Directors Meeting, Nov. 21, 2019) (*in camera*) ( [REDACTED] ); PX9090 (Roche) at 019 (Cowen, The Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sep. 18, 2020) (stating that it “is clear that CMS reimbursement [for asymptomatic cancer screening tests] will require FDA approval”).
510. A Premarket Approval (“PMA”) is a regulatory approval from the FDA that applies to high-risk, Class III diagnostic tests. (Febbo (Illumina) Tr. 4324; Ofman (Grail) Tr. 3319).
511. [REDACTED]
- [REDACTED]
- (Chudova (Guardant) Tr. at 1208-09) (*in camera*).
512. Unless a MCED test can be shown to be “substantially equivalent to a legally marketed predicate device,” the test will be “automatically classified under the [Food, Drug, and Cosmetic Act] into class III, which generally requires PMA approval.” (PX0043 at 043 (Grail 2020 Form S-1)).
513. Galleri will be considered a Class III medical device and will require Premarket Approval. (Febbo (Illumina) Tr. 4445; PX7099 (Febbo (Illumina) Dep. at 83-84); PX0043 at 043-44 (Grail 2020 Form S-1)).
514. [REDACTED] (Conroy (Exact) Tr. 1548-49; *see also* Rabinowitz (Natera) Tr. 394-95 (*in camera*) ([REDACTED] )).
515. The quality of a product is part of safety and efficacy with respect to FDA approval. (Conroy (Exact) Tr. 1548-49).
516. Dr. Ofman testified at trial that the FDA’s requirements for a PMA approval exceed those to meet LDT standards: “[T]he FDA has many additional requirements in terms of quality, manufacturing, inspections. The evidence requirements are quite different.” (Ofman (Grail) Tr. 3319). “[T]here’s just a lot more to getting an FDA approval above and beyond

what it takes to get CAP/CLIA certification.” (Ofman (Grail) Tr. 3319; *see also* Bishop (Grail) Tr. 1345 (stating that a PMA has “an entirely different set of requirements” than an LDT).

- 517. [REDACTED] (Rabinowitz (Natera) Tr. 395 (*in camera*)).
- 518. A PMA requires submitting a lengthy application involving clinical and analytical validation data collected during clinical trials using the device. (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
- 519. According to Dr. Ofman, analytical validation means ensuring that a test measures what it purports to measure at certain levels of precision. (Ofman (Grail) Tr. 3284).
- 520. Analytical validation is typically followed by clinical validation, which means demonstrating that a test performs as indicated to detect the given disease in the intended use population. (Ofman (Grail) Tr. 3284-85).
- 521. Clinical validation is critical for the commercialization of a test such as Galleri, as it is necessary to receive FDA approval, Medicare coverage, and reimbursement by private insurance. (*See* Gao (Singlera) Tr. 2886-87; PX7099 (Febbo (Illumina) Dep. at 36) (testifying that clinical validation is necessary for FDA approval); *see also* PX4160 (Grail) at 094 (Grail, Board of Directors Meeting, Nov. 10, 2020) (*in camera*) ([REDACTED])).
- 522. Like clinical validation, demonstrating clinical utility requires evidence that a test can detect disease in the intended use population. (Qadan (Illumina) Tr. 4110).
- 523. Establishing clinical utility also involves assessing how a test’s results may impact patient management and outcomes. (Qadan (Illumina) Tr. 4110-11).
- 524. Dr. Navathe testified that because evidence of clinical validity and clinical utility overlap, a single study may develop evidence of both clinical validity and clinical utility, such as Grail’s PATHFINDER 1, Clinical Practice Learning Program, Strive, Summit, and NHS studies. (RX3853 (Navathe Trial Dep. at 182)).
- 525. [REDACTED] (PX4389 (Grail) at 036 (*in camera*) ([REDACTED])).
- 526. Evidence of clinical utility relates to how a test changes patient management and outcomes. (PX7084 (Qadan (Illumina) Dep. at 14) (“[C]linical utility’ . . . “mean[s] how does the test change the management of a patient, resulting in better outcomes.”)).
- 527. Dr. Navathe testified that interventional studies are an important step in the generation of clinical utility evidence. (RX3853 (Navathe Trial Dep. at 183) (“Q: What evidence of

clinical utility is expected to be generated by PathFinder 1? A: The effectiveness, the real world effectiveness, of implementing Galleri into clinical practice.”)).

528. MCED test developers must conduct clinical trials for their tests to obtain regulatory approval. (Della Porta (Grail) Tr. 584; *see also* Lengauer (Third Rock Ventures) Tr. 170 (explaining that for FDA approval, test developers must undergo a “registrational trial,” which allows the FDA to evaluate the benefit-to-risk ratio of a test or device).

529. [REDACTED] (See, e.g., Rabinowitz (Natera) Tr. 302-303; PX7091 (Lengauer (Third Rock Ventures) Dep. at 134-135 (*in camera*)) [REDACTED]; PX7077 (Chahine (Helio) Dep. at 32-33 (*in camera*)) [REDACTED]).

530. [REDACTED] } (PX7111 (Fesko (Natera) Dep. at 33-34); PX7050 (Nolan (Freenome) IHT at 67-70, 72) (*in camera*)).

531. As part of the FDA’s review of a PMA, the FDA will typically inspect the manufacturer’s facilities for compliance with Quality System Regulation (QSR) requirements, which impose requirements related to design controls, manufacturing controls, documentation, and other quality assurance procedures. (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

532. Grail employees have already begun discussions with the FDA regarding a PMA application for Galleri. (Bishop (Grail) Tr. 1345).

533. Grail’s S-1 explains that the FDA is continuing to gather input from industry, academic, and clinical stakeholders to “inform its thinking on how to assess” MCED tests. (PX4082 (Grail) at 047 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

534. [REDACTED] } (PX4430 (Grail) at 026, 028 (*in camera*); PX4475 (Grail) at 012 [REDACTED]) (*in camera*)).

535. [REDACTED] (PX4475 (Grail) at 081 (*in camera*)).

a) Single-Site IVDs

536. A single-site PMA is also referred to as a single-site IVD. (Goswami (Illumina) Tr. 3186).
537. A single-site, or centralized, IVD test is approved by the FDA to run in a single approved lab, typically the MCEd test developer’s own laboratory. (Goswami (Illumina) Tr. 3186; PX7112 (Bailey (PGDx) Dep. at 14); PX7093 (Young (Illumina) Dep. at 43-44); PX7065 (Aravanis (Illumina) IHT at 139-140); PX7055 (Otte (Freenome) IHT at 41-42); PX7063 (Berry (Illumina) IHT at 202); PX7064 (Goswami (Illumina) IHT at 28-31); PX7040 (Getty (Guardant) IHT at 78-79); PX7049 (Bailey (PGDx) IHT at 25)).
538. [REDACTED] } (PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7100 (Chudova (Guardant) Dep. at 55-57) (*in camera*)).
539. [REDACTED] (PX7069 (Bishop (Grail) IHT at 94-95) (explaining that FDA approval is “a prerequisite for getting broad-based reimbursement. And secondly, it’s something that confirms the performance attributes of the test”); PX7055 (Otte (Freenome) IHT at 32-33) (*in camera*) ([REDACTED] )).

b) Distributed or Kitted IVDs

540. A distributed or “kitted” IVD is an IVD test that has received PMA approval from the FDA permitting analysis by independent testing providers, such as hospitals or large reference labs like LabCorp or Quest. (Goswami (Illumina) Tr. 3186-87; Leite (Illumina) Tr. 2150; PX7049 (Bailey (PGDx) IHT at 68-69); PX7063 (Berry (Illumina) IHT at 202); PX7112 (Bailey (PGDx) Dep. at 14-18); PX7093 (Young (Illumina) Dep. at 44)).
541. An approved IVD test must “lock-in” its specific NGS instrument, reagents, and other system components as part of the final FDA approval. (PX7045 (Chudova (Guardant) IHT at 73-74); PX7044 (Stahl (Invitae) IHT at 60-61)).
542. Modifying any component of the approved IVD could require conducting an additional clinical trial with the modified component. (PX7045 (Chudova (Guardant) IHT at 73–74)).
543. Because the test is locked-in with a particular NGS platform, switching to new technology platforms is difficult. (PX7045 (Chudova (Guardant) IHT at 73-74); PX7044 (Stahl (Invitae) IHT at 60-61)).
544. The distributed kit IVD test developer has “responsibility for quality control and quality analysis” of the distributed kit IVD test. (Goswami (Illumina) Tr. 3187).
545. A distributed kit IVD test developer must follow FDA guidelines and submit to regular FDA audits following PMA approval of a distributed kit IVD. (Goswami (Illumina) Tr. 3187).



546. [REDACTED]  
(PX7040 (Getty (Guardant) IHT at 81-82) (*in camera*)).
547. [REDACTED] (PX7055 (Otte (Freenome) IHT at 40-41) (*in camera*); PX7049 (Bailey (PGDx) IHT at 25)).
548. [REDACTED]  
(PX7094 (Nolan (Freenome) Dep. at 234-35) (*in camera*)).
549. Helio’s Dr. Chahine testified that, [REDACTED]  
[REDACTED] (PX7077 (Chahine (Helio) Dep. at 19) (*in camera*)).
550. [REDACTED] } (PX7100 (Chudova (Guardant) Dep. at 57-58) (*in camera*)).
551. An MCED test developer that relies on Illumina sequencing would need an IVD agreement with Illumina to distribute its test to third-party labs. (Goswami (Illumina) Tr. 3262-63).

### 3. Payer Reimbursement

552. [REDACTED] (PX7055 (Otte (Freenome) IHT at 34-35) (*in camera*); PX7058 (Conroy (Exact) IHT at 87-88) (*in camera*)).
553. [REDACTED] } (PX7083 (Bishop (Grail) Dep. at 145-146) (*in camera*)).
554. [REDACTED] } (Conroy (Exact) Tr. 1734; Bishop (Grail) Tr. 1343-44; PX7055 (Otte (Freenome) IHT at 32-33) (*in camera*); PX7068 (Perettie (FMI-Roche) IHT at 33) (*in camera*)).
555. There are two major sources of insurance in the United States: The Centers for Medicare & Medicaid Services (“CMS”) and private payers. (Chahine (Helio) Tr. 1029).
556. Illumina admits that “[t]o make Galleri broadly available in the U.S., it is essential that Galleri obtain coverage from both Medicare and private insurers.” (PX6060 (Illumina) at 023 (Illumina’s Responses & Objections to FTC’s First Set of Interrogatories)).

557. Broad-based adoption refers to coverage by government insurers and private insurers. (Bishop (Grail) Tr. 1330).
558. Reimbursement of an MCED test will depend on many factors, including sensitivity and specificity of the test. (Conroy (Exact) Tr. 1735).
559. Reimbursement of an MCED test will also depend on whether the test is reliable, safe, effective, and medically necessary. (Conroy (Exact) Tr. 1735).
560. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 163-165) (*in camera*)).
561. Respondents' expert Dr. Carlton [REDACTED] } (RX3864 (Carlton Rebuttal Report) ¶ 13) (*in camera*)).
562. Respondents' expert Dr. Abrams [REDACTED] } (PX6097 (Abrams Rebuttal Report) ¶ 30) (*in camera*)).
563. Grail's Galleri test is not yet covered by Medicare or private insurance. (PX7083 (Bishop Grail) Dep. at 87)).
- a) Private Payers
564. [REDACTED] (Bishop (Grail) Tr. 1331-33; Della Porta (Grail) Tr. 456-58; Ofman (Grail) Tr. 3371-72 (*in camera*)).
565. [REDACTED] } (Bishop (Grail) Tr. 1401; Ofman (Grail) Tr. 3371-72 (*in camera*); PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
566. In its 2020 Form S-1 filing, Grail stated that “[m]any of the nation’s premier healthcare institutions have robust programs in population health management and precision management” and noted that one of Grail’s “planned strategies upon commercial launch is to offer Galleri at select certain [sic] regional health systems.” (PX0043 at 115 (Grail 2020 Form S-1)).
567. As of trial, Grail [REDACTED] } health systems. (Ofman (Grail) Tr. 3372 (*in camera*)).

568. [REDACTED] } (PX4610 (Grail) at 002-003 (Email from Stephanie Gutendorf, Grail, to Grail “Weekly Market Access Summary” distribution list, July 19, 2021) (*in camera*)).
569. Self-insured employers are employers that are responsible for the healthcare costs of their employees. (Della Porta (Grail) Tr. 457-58).
570. As of trial, Grail { [REDACTED] } self-insured employers. (Ofman (Grail) Tr. 3374-75 (*in camera*)).
571. [REDACTED] } (PX4610 (Grail) at 003-004 (Email from Stephanie Gutendorf, Grail, to Grail “Weekly Market Access Summary” distribution list, July 19, 2021) (*in camera*)).
572. Concierge practices are primary care practices in which patients pay a fee for preferred access to doctors. (Bishop (Grail) Tr. 1333; Della Porta (Grail) Tr. 462).
573. Grail estimates that the total addressable U.S. market for Galleri within physician-directed channels (including concierge practices) is 1 million individuals. (PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
574. [REDACTED] } (Della Porta (Grail) Tr. 464; Ofman (Grail) Tr. 3372 (*in camera*) ([REDACTED])).
575. As of trial, Grail { [REDACTED] } Galleri tests. (Ofman (Grail) Tr. 3375 (*in camera*)).
576. Galleri is not covered by private insurance. (Bishop (Grail) Tr. 1323; 1401-02).
577. Grail Chief Medical Officer Joshua Ofman testified: “we don’t expect that large U.S. payers are going to provide coverage for the [Galleri] test without FDA approval.” (Ofman (Grail) Tr. 3319-20).
578. Grail CEO Hans Bishop testified that “PMA approval with FDA” is a “prerequisite” to making Galleri “accessible to many more patients than are in [Grail’s] starting channels [made up of health systems, large self-insured employers, and concierge practices].” (Bishop (Grail) Tr. 1402-03).
579. Dr. Lengauer explained that FDA approval is “very, very important for acceptance of tests in the community” and “is very often a requirement for potential reimbursement of the test.” (Lengauer (Third Rock Ventures) Tr. 170).

580. FDA approval also lends credibility to MCED tests, which many primary care physicians will likely require before prescribing MCED tests to patients. (Lengauer (Third Rock Ventures) Tr. 231).

b) CMS

581. Individuals 65 or over are covered by Medicare. (Freidin (Grail) Tr. 2991).

582. [REDACTED] } (deSouza (Illumina) Tr. 2414; Ofman (Grail) Tr. 3319-20; PX4172 (Grail) at 059 (Grail, Board of Directors Meeting, Nov. 21, 2019) (*in camera*) ([REDACTED])); (Conroy (Exact) Tr. 1734; Chahine (Helio) Tr. 1054-55 (*in camera*); ([REDACTED])); Febbo (Illumina) Tr. 4335).

583. CMS stated in January 2021 that it would require FDA approval to grant reimbursement for early cancer detection testing. (Chahine (Helio) Tr. 1029).

584. The processes for receiving FDA approval and CMS reimbursement are not the same. (Freidin (Grail) Tr. 2981).

585. First, a test must get FDA approval, and then CMS performs a cost-benefit analysis to see whether it will pay for the test. (Freidin (Grail) Tr. 2981-82).

586. According to Mr. Conroy, an MCED test “would be viable only as a niche product” in the United States if it was not covered by Medicare. (Conroy (Exact) Tr. 1734-35).

587. [REDACTED] } (Ofman (Grail) Tr. 3352-53 (*in camera*)).

588. Congress introduced a bill called the Medicare MCED Screening Coverage Act that targets early cancer screening. (Bishop (Grail) Tr. 1323-24).

589. The Medicare MCED Screening Coverage Act would give CMS the authority to reimburse cancer screening tests including Galleri once approved by the FDA. (Bishop (Grail) Tr. 1324).

590. Grail has advocated in favor of and supported the passage of the Medicare MCED Screening Coverage Act. (Bishop (Grail) Tr. 1324).

591. [REDACTED] (Ofman (Grail) Tr. 3356 (*in camera*)).

592. [REDACTED]  
[REDACTED]  
(Ofman (Grail) Tr. 3354 (*in camera*)).

c) USPSTF

593. [REDACTED]  
[REDACTED]  
[REDACTED] } (PX7110 (Conroy (Exact) Dep. at 58-59) (*in camera*)).

594. [REDACTED]  
[REDACTED]  
[REDACTED] (PX7058 (Conroy (Exact) IHT at 137 (*in camera*))).

595. [REDACTED]  
[REDACTED] } (PX7058 (Conroy (Exact) IHT at 27) (*in camera*)).

596. [REDACTED]  
[REDACTED]  
[REDACTED] } (PX7110 (Conroy (Exact) Dep. at 59-60 (*in camera*))).

597. [REDACTED]  
[REDACTED]  
[REDACTED] } (PX7058 (Conroy (Exact) IHT at 29-30) (*in camera*)).

598. When USPSTF approves a product it “allows Medicare to cover a new screening test if that test is recommended by USPSTF. The way the Medicare Act works, which is under

the Social Security Act, is that Medicare only pays for taking care of people who are sick and, unless otherwise specifically spelled out, it doesn't pay for preventive services. So it's only if – either in the law, like for mammography or colon cancer screening, where the Medicare Act specifically allows and provides for Medicare to pay for certain services or if the USPSTF ranks a new service as an A – or B-rated service, then Medicare can make the decision to cover the test.” (PX7058 (Conroy (Exact) IHT at 30)).

599. “USPSTF is hugely influential in whether a new cancer screening technology ever gets to see the light of day and used by people throughout the country.” (PX7058 (Conroy (Exact) IHT at 30-31)).

600. [REDACTED] } (Conroy (Exact) Tr. 1629 (*in camera*)).

601. [REDACTED] } (Ofman (Grail) Tr. 3355 (*in camera*)).

602. [REDACTED] } (Ofman (Grail) Tr. 3355 (*in camera*)).

603. [REDACTED] } (Ofman (Grail) Tr. 3355 (*in camera*)).

604. [REDACTED] } (Ofman (Grail) Tr. 3355 (*in camera*)).

**III. THE RELEVANT PRODUCT MARKET IS THE MARKET FOR THE RESEARCH, DEVELOPMENT, AND COMMERCIALIZATION OF MCED TESTS**

605. [REDACTED] (See, e.g., PX4082 (Grail) at 008-009 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7100 (Chudova (Guardant) Dep. at 15-16); PX7094 (Nolan (Freenome) Dep. at 252-253) (*in camera*); PX4116 (Grail) at 013 (Email from M. Podoll, Morgan Stanley, to A. Freidin, Grail, et al., attaching IPO Roadshow Video Outline: Project Galileo, Aug. 2020); PX8392 (Exact) at 002 (Pipeline Review, Jan. 2021) (*in camera*); PX7051 (Lengauer (Third Rock Ventures) IHT at 27-29) (*in camera*)).

606. [REDACTED] (See, e.g., PX2005 (Illumina) at 004-005, 009, 013 (Illumina, ScreenCo – Early Cancer Detection on a Global Scale Presentation, 2015) ([REDACTED]); PX5027 (Illumina) at 015 (Illumina, Board of Directors Meeting, Aug. 3, 2020) (*in camera*)).

607. Witnesses similarly described MCED tests. (*See infra* Section VI. (Competitors Are Racing to Develop MCED Tests).

608. [REDACTED] (Bishop (Grail) Tr. 1373; *see also* Cance (American Cancer Society) Tr. 609).

609. [REDACTED] } (*See* PX4082 (Grail) at 008-009 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX4116 (Grail) at 013 (Email from M. Podoll, Morgan Stanley, to A. Freidin, Grail, et al., attaching IPO Roadshow Video Outline: Project Galileo, Aug. 2020); PX2169 (Illumina) at 048 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

610. [REDACTED] (*See* PX2169 (Illumina) at 048 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*); PX4289 (Grail) at 002, 004-005 (Email and attachment from J. Ofman, Grail, to all Grail employees, Apr. 9, 2020); PX4159 (Grail) at 011, 014-015 (Grail, Investor Presentation, Aug. 2020); *see also* PX5027 (Illumina) at 017 [REDACTED] ( [REDACTED] } (*in camera*)).

**A. BLOOD-BASED CANCER DETECTION TESTS DESIGNED FOR PURPOSES OTHER THAN CANCER SCREENING ARE NOT SUBSTITUTES FOR MCEDS**

**1. Other Blood-Based Cancer Detection Tests Serve a Different Function**

611. Guardant’s R&D efforts include three oncology related clinical applications—a therapy selection test, a minimal residual disease test (“MRD”), and a cancer screening test. (Chudova (Guardant) Tr. 1138-39). These three applications span the different phases of a cancer diagnosis, from an undiagnosed patient to patients currently undergoing various stages of treatment. (Chudova (Guardant) Tr. 1138-39).

612. [REDACTED] } (PX4074 (Grail) at 066 (Grail, Science, Medicine, and Technology Board Subcommittee Meeting, 2020-03-02 Pre-Read, Mar. 2, 2020) (*in camera*)).

613. [REDACTED] } (Rabinowitz (Natera) Tr. 287-289, 354 (*in camera*)).

614. An MRD test monitors responsive therapy in treating cancer, including immunotherapy. (Rabinowitz (Natera) Tr. 287-289).

615. [REDACTED] (Rabinowitz (Natera) Tr. 353-54 (*in camera*)).

616. Grail is developing three separate blood-based tests—DAC, MRD, and MCED tests—for three separate purposes. [REDACTED]

617. Grail’s Mr. Kollu testified that MRD is a “different product” which is sometimes “referred to as the post-diagnostic product.” “[T]he MRD product aims to be able to give the doctor an advance warning if [ ] cancer is about to recur.” (PX7062 (Kollu (Grail) IHT at 31-32)).

a) Therapy Selection Tests Serve a Different Purpose

618. [REDACTED] } (PX7061 (Davy (Illumina) IHT at 153) (*in camera*)).

619. A blood-based therapy selection test identifies the mutational profile of a tumor using a blood sample, instead of an invasive biopsy procedure, to help identify a drug therapy that works well when a patient’s tumor contains a specific mutation. (Chudova (Guardant) Tr. 1150).

620. For example, Guardant’s current flagship product—named Guardant360—is a therapy selection test that analyzes a blood sample to help clinicians choose the appropriate treatment for patients diagnosed with advanced cancer. (Chudova (Guardant) Tr. 1146-47).

621. Therapy selection tests are intended for patients with “advanced cancer” and assist the physician with determining “the course of therapy they will pursue” to treat the cancer. (See PX7040 (Getty (Guardant) IHT at 44-45) (describing Guardant360, a 74-gene therapy selection assay)).

622. [REDACTED] (PX7061 (Davy (Illumina) IHT at 153) (*in camera*)).

623. Oncologists typically order therapy selection tests for patients who have already received a cancer diagnosis. (PX7080 (Silvis (Tempus) Dep. at 30-32)).

b) Minimal Residual Disease Tests Serve a Different Purpose

624. Minimal Residual Disease tests are used to determine whether remnants of cancer remain in a patient who has been treated for cancer. (PX7092 (Ofman (Grail) Dep. at 94)).



- 625. An MRD test is used with early-stage cancer patients to analyze any traces of residual disease in the blood after treatment. (Chudova (Guardant) Tr. 1151; PX4082 (Grail) at 012 (Email attaching Grail 2020 S-1/Amended, Sept. 2020) (describing MRD tests as intended for monitoring for cancer in “[p]atients with cancer, primary or metastatic, following completion of therapy”); PX4133 (Grail) at 006 (Grail, Investor Presentation, Aug. 2020) (“Minimal Residual Disease product designed to detect cancer after diagnosis and treatment”)).
- 626. An MRD test can help physicians determine whether to perform additional treatments on a patient after a resection of a cancerous tumor based on the potential for any remaining disease to progress. (Chudova (Guardant) Tr. 1151-52).
- 627. The clinical context for an MRD test is different than for a therapy selection test, in that a physician uses an MRD test for patients with earlier stages of cancer and a therapy selection test for patients with later-stages of cancers. (Chudova (Guardant) Tr. 1146-47, 1151-52).
- 628. An MRD test is given to patients who have already been diagnosed with cancer, which differs from a cancer screening test that is given to asymptomatic patients who have not yet been diagnosed with cancer. (PX7092 (Ofman (Grail) Dep. at 94-95).

c) Diagnostic Aid to Cancer Tests Serve a Different Purpose

629. A diagnostic aid to cancer (“DAC”) test helps a doctor confirm or rule out a cancer diagnosis. (PX7069 (Bishop (Grail) IHT at 69-70); PX7072 (deSouza (Illumina) IHT at 160-61)).

630. [REDACTED] }  
 [REDACTED] see also Della Porta (Grail) Tr. 514 (*in camera*); PX4074 (Grail) at 067 (Grail, Science, Medicine, and Technology Board Subcommittee Meeting, 2020-03-02 Pre-Read, Mar. 2, 2020) (*in camera*); PX4133 (Grail) at 030 (Grail, Investor Presentation, Aug. 2020)).

631. [REDACTED]  
 [REDACTED] (PX4337 (Grail) at 005-006)  
 [REDACTED] (*in camera*)).

632. [REDACTED]  
 [REDACTED] (PX4337 (Grail) at 005)

[REDACTED] (*in camera*)).

633. [REDACTED] } (PX4337 (Grail) at 006-007 [REDACTED] (*in camera*)).

**B. OTHER CANCER SCREENING TESTS ARE NOT SUBSTITUTES FOR MCED TESTS**

634. As Grail’s Chief Medical Officer Dr. Ofman testified at trial, single-cancer screening tests are “very different” from MCED tests: “People who want to do single-cancer screening tests, that’s very different than doing a multicancer early detection test.” (Ofman (Grail) Tr. 3311).

**1. USPSTF Cancer Screening Methods Are Complementary to MCED Tests**

635. USPSTF recommends a [REDACTED] } (PX5027 (Illumina) at 018 [REDACTED] (*in camera*)).

636. [REDACTED] } (PX2009 (Illumina) at 017 (Illumina, April BoD M&A Strategy Presentation, Apr. 28, 2020) (*in camera*); Lengauer (Third Rock Ventures) Tr. 168-169).

637. Grail explained in a document to address common questions and misperceptions about its test: “There is a misperception that current single cancer screening tests alone are doing the job. These critically important screens are saving lives, but given performance and compliance they collectively are only finding about 16% of the US cancer incidence.” (PX4164 (Grail) at 004 (Key Points to Address Common Questions and Misperceptions, Oct. 26, 2020)).

a) MCED Tests Offer Unique Benefits That Existing Screening Methods Do Not

638. Grail documents explain that MCED tests are being designed to detect cancer earlier than traditional methods of cancer detection. (PX0037 (Grail) at 002-006 (Grail Investor Call Script, Jan. 10, 2016)).

639. Mr. Bishop—Grail’s CEO—testified that MCED tests will have the ability to detect cancer much earlier. (PX7069 (Bishop (Grail) IHT at 122-23) (Explaining that Grail’s Galleri differs from current screening methodologies: “The first is, it’s a multicancer test. The – you know, the problem with cancer mortality associated with late detection is that 70 percent of cancer deaths are occurring – in spite of all those tests we just talked about, Will, 70 percent of cancer deaths are occurring in cancers where there is absolutely zero early

detection, so the first way that Galleri differs is it gives us a way looking for all those cancers where today there is no early detection at all.”)).

640. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 190 (*in camera*); PX7091 (Lengauer (Third Rock Ventures) Dep. at 148-50) (*in camera*) ([REDACTED] [REDACTED] })).

641. Blood-based cancer screening tests are generally safer and less uncomfortable for the patient than other current cancer screening methods such as colonoscopy, mammogram, or tissue biopsy because it is generally easier on a patient for a clinician to draw a blood sample than to remove a tissue sample or perform a procedure for which the patient requires sedation or anesthesia. (*See, e.g.*, PX0059 at 011 (Guardant 2020 10-K); PX8313 (Guardant) at 002 (Guardant, Guardant 360 CDx Original PMA Application (M180021) - Module 5, Attachment 6-1: Background Information on Liquid Biopsy for NGS Tests); PX7044 (Stahl (Invitae) IHT at 45); PX7040 (Getty (Guardant) IHT at 50-51); PX7042 (Gao (Singlera) IHT at 25-26); PX7068 (Perettie (FMI-Roche) IHT at 22-23)).

642. Dr. Cance—from the American Cancer Society—also explained that blood-based biopsy tests are a less invasive screening method than tissue tumor biopsies. (Cance (American Cancer Society) Tr. 608-09; PX8398 (Cance (American Cancer Society) Decl. ¶ 8)).

643. Some advantages of blood-based biopsies over tissue biopsies include a quicker turnaround time and the ability to repeat the test over time to observe changes. (*See* PX7040 (Getty (Guardant) IHT at 51-54); PX0043 at 005, 101 (Grail, Form S-1 Registration Statement, Sept. 9, 2020); PX7044 (Stahl (Invitae) IHT at 44-46)).

644. The benefits of blood-based tests over tumor-based tests will likely lead to higher patient compliance, as patients that were previously reluctant to undergo invasive tests like a colonoscopy agree to receive non-invasive blood-based tests. Higher rates of cancer screening should, in turn, produce better patient outcomes. (*See* PX7040 (Getty (Guardant) IHT at 27-31); PX2022 (Illumina) at 009 (Cowen, The Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sept. 18, 2020) (among the benefits of blood-based tests: “Ease of use/better outcomes – broader screening, expanded use of optimal targeted therapeutic decision making (even in the community setting where most cancers are treated), earlier recurrence detection.”)).

645. As Guardant’s SVP of Commercial, Bill Getty, testified, “If you could find those [cancers] early on, you may be able to intervene and actually stop the course of that disease and therefore spare that person of the mortality associated with the disease.” (PX7040 (Getty (Guardant) IHT at 33)).

(1) Witnesses and Ordinary Course Documents State That MCED Tests and USPSTF Screening Tests Are Complements

646. Market participants, including the parties, recognize that MCED tests should “complement” these “standard of care screening tests . . . rather than replace them.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 51-52); *see also* PX7092 (Ofnan (Grail) Dep. at 92) (“Grail’s multi-cancer early detection test is a complement to, not a replacement for, the standard of care single-cancer screening tests.”); PX2165 (Illumina) at 011 (Exact Sciences Q3 2020 Earnings Call, Oct. 27, 2020)).

647. [REDACTED] (PX7040 (Getty (Guardant) IHT at 154-155); PX7051 (Lengauer (Third Rock Ventures) IHT at 176) (*in camera*); PX7083 (Bishop (Grail) Dep. at 24-25)).

648. “CancerSEEK as a test is meant to be in addition to standard of care.” Thrive wants “an individual to continue to comply with standard of care, like mammography or colonoscopy, and these tests should augment, which is an additional standard of care to detect cancer.” (Lengauer (Third Rock Ventures) Tr. 167-68).

649. Dr. Vogelstein testified that the goal of blood-based cancer screening tests is not to replace the existing standard of care screening tests because “standard of care screening tests have been extensively evaluated over a number of years” and it “would be a disservice to the public” for patients to “use blood tests to substitute for the currently recommended screening tests.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 51-52)).

650. As the Grail website explains, “[t]he Galleri test is intended to be complementary to, and not a replacement of, U.S. guideline-recommended cancer screening.” (PX0063 at 001 (Grail, Galleri Multi-Cancer Early Detection Test, <https://grail.com/galleri/> (last visited Apr. 29, 2021))).

651. Illumina also acknowledged in its due diligence of Grail that Grail’s MCED test would be [REDACTED] } (PX2167 (Illumina) at 003 (Illumina, Early Cancer Detection: Market Access / Health Economic Considerations, circulated June 24, 2020) (emphasis in original) (*in camera*)).

652. Grail in its Form S-1 told potential investors that “Galleri is designed to detect unscreened cancers and to complement the United States Preventive Services Task Force (USPSTF)-recommended screenings (specifically, lung for high-risk smokers, breast, cervical, prostate, and colorectal cancers have recommended screenings).” (PX0043 at 005 (Grail, Form S-1 Registration Statement, Sept. 9, 2020)).

653. [REDACTED] } (PX4031 (Grail) at 016, 062-067

(Grail, Master Slide Deck V1\_061520) (*in camera*) { [REDACTED] } (PX4031 (Grail) at 069-070 (Grail, Master Slide Deck\_V1\_061520) (*in camera*)).

- 654. Grail witnesses, such as ex-CEO Hans Bishop, testified that Galleri should be used alongside existing standard of care screening tests. (Bishop (Grail) Tr. 1320-21).
- 655. Grail’s Dr. Jamshidi—Senior Vice President of Data Sciences—testified: “So our focus is not to replace [existing screening methods]. It’s very much to complement the standard screening approaches that are available today so that we can address this unmet need around cancers that don’t have any screenings available to them.” (PX7103 (Jamshidi (Grail) Dep. at 38-39)).
- 656. Existing standard of care single-cancer screening tests are “optimized” for the single cancers they detect. (Bishop (Grail) Tr. 1321). Mr. Bishop explained that, in comparison to the existing standard of care screening tests, Galleri is not as sensitive:

[W]ithout exception, the single-cancer tests used today for prostate, cervix, breast and colon -- and I can list the particular tests that are regarded as standard of care today -- their detection rate for those single cancers at their specificity is higher than the detection rate for those individual single cancers that the Galleri test has. That’s the essential reason why these tests should be used alongside each other.

(Bishop (Grail) Tr. 1392).

- 657. Respondents’ expert, Dr. Abrams, testified that he “would not substitute a multicancer early detection test for any of the standard recommended screening tests.” (Abrams Tr. at 3631; *see also* PX7137 (Abrams Dep. at 34); PX6097 (Abrams Rebuttal Report) ¶ 31 (*in camera*) ([REDACTED])).
- 658. Exact Sciences’ CEO explained that [REDACTED] (Conroy (Exact) Tr. 1647-48 (*in camera*); *see also* Lengauer (Third Rock Ventures) Tr. 167-68).
- 659. Mr. Getty does not expect Guardant’s MCED test to replace current screening methodologies. He explained, for example, that “the goal of noninvasive screening in large part is to have a noninvasive test up front that says positive or negative, and if you’re positive, then go for the colonoscopy.” (PX7040 (Getty (Guardant) IHT at 154)).

**2. Other Non-USPSTF Single-Cancer Blood-Based Tests Are Not Close Substitutes for MCED Tests**

- 660. [REDACTED]

[REDACTED]  
[REDACTED] (PX4031 (Grail) at 006 (Master Slide Deck V1\_061520) (in camera)).  
[REDACTED] } (See  
PX4031 (Grail) at 018, 020 (Master Slide Deck\_V1\_061520) (in camera) (identifying  
benefits of “Multi-Cancer Early Detection Test” including low false positives, maximizing  
compliance, high PPV, and avoiding overdiagnosis, among others).

661. [REDACTED]  
[REDACTED] (PX4430 (Grail) at 012  
(in camera)).  
[REDACTED] (PX4430 (Grail) at 012  
(in camera)).

662. Grail told investors that “[m]ulti-cancer early detection is needed (single cancer screening  
won’t get us there, as detects 15-20% of cancers).” (PX4133 (Grail) at 007 (Investor  
Presentation, Aug. 2020)).

a) MCED Tests Offer Unique Benefits from Single-Cancer Screening  
Tests

663. Grail’s Galleri tests screen for more than one type of cancer, including cancer types that  
currently do not have existing screening mechanisms. [REDACTED]  
[REDACTED]

664. In a PowerPoint regarding its IPO Roadshow Video, Grail noted that “screening for single  
cancers individually ‘misses the forest for the trees’” as “[a]pproximately 3x as many  
cancer cases can be found with a test that is able to detect multiple cancers at the [REDACTED]  
[REDACTED] see  
also (PX4031 (Grail) at 013 (Master Slide Deck V1\_061520) (in camera))  
[REDACTED] })).

665. Illumina’s Dr. Aravanis explained in an ordinary course document that “[t]he potential  
benefits of a multi-cancer test are much larger than that of a single cancer test. For cancers  
like pancreatic cancer which have lower prevalence, but very deadly, it would be difficult  
to implement as a single cancer test vs part of a multi-cancer test that has a much higher

aggregate prevalence.” (PX2346 (Illumina) at 001 (Email from A. Aravanis, Illumina, to J. Cunningham, Illumina, Nov. 25, 2020)).

666. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*); Gao (Singlera) Tr. 2873-74, 2914; PX7105 (Getty (Guardant) Dep. at 13-14)).

667. Dr. Ofman testified at trial that single cancer screening tests are “very different” from MCED tests: “People who want to do single-cancer screening tests, that’s very different than doing a multicancer early detection test.” (Ofman (Grail) Tr. 3311).

668. According to Dr. Ofman, the intended use of an MCED test differs from a single cancer screening test: “[W]hen you order Galleri as a physician, you’re not suspecting any particular type of cancer. That’s why you order Galleri.” (Ofman (Grail) Tr. 3312).

669. Grail’s documents explain that MCED tests offer a unique benefit from single cancer tests in that MCED tests “[d]etect[] multiple deadly cancer types at early stages rather than creating multiple single cancer tests which may be logistically impractical and more costly overall.” (PX4012 (Grail) at 001 (Email from K. Grossman, Grail, to K. Eng, Grail, July 11, 2019)).

670. [REDACTED] (See PX2169 (Illumina) at 048 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 30, 2020) (*in camera*); PX4289 (Grail) at 002, 004-006 (Email from J. Ofman, Grail, to All Grail Employees, attaching comment for FDA Workshop, Apr. 9, 2020); PX4159 (Grail) at 015 (Email from J. Craighead, Grail, to Grail Board of Directors et al., attaching Early Cancer Detection - Investor Presentation, Aug. 2020); see also PX5027 (Illumina) at 025 [REDACTED] (*in camera*)).

b) [REDACTED]

671. [REDACTED] (PX5027 (Illumina) at 017 (*in camera*); see PX4031 (Grail) at 011 (Master Slide Deck V1 061520) (explaining that [REDACTED] (*in camera*)).

672. [REDACTED]

(PX5027 (Illumina) at 015  
(*in camera*)).

(PX5027 (Illumina) at 017  
(*in camera*)).

c) Witnesses and Documents from Illumina and Grail Show That Single-Cancer Tests Do Not Compete with MCED Tests

673. At trial, Grail’s Dr. Ofman explained that single cancer tests are “not really competing” with MCED tests. (Ofman (Grail) Tr. 3311).
674. Dr. Ofman testified in his deposition that “GRAIL’s multi-cancer early detection test is a complement to, not a replacement for, the standard of care single-cancer screening tests.” (PX7092 (Ofman (Grail) Dep. at 92)).
675. Dr. Ofman claimed at trial that he did not expect that Galleri would compete with companies developing single-cancer blood-based tests because “single-cancer screening tests” are “very different than doing a multicancer early detection test.” (Ofman, (Grail)Tr. 3310-11). Instead, Galleri is “a complement to . . . single-cancer screening tests.” (Ofman (Grail) Tr. 3308-09).
676. Dr. Ofman explained that Galleri “is not intended on any level to replace” the existing single-cancer screening tests. (Ofman (Grail) Tr. 3309).
677. Dr. Ofman testified, “if you have a negative Galleri test, you still want to encourage the individual to get their single-cancer screening tests.” (Ofman (Grail) Tr. 3310).
678. Illumina’s Dr. Aravanis testified at trial that Galleri is not intended to compete with single cancer tests because single-cancer screening tests “are to be used in current standard of care applications.” (Aravanis (Illumina) Tr. 1921).
679. Grail documents show that Grail had originally planned on developing both single-cancer tests as well as an MCED test. (*See* PX2712 (Illumina) at 009 (Email from M. Nguyen, Illumina, to P. Scagnetti, Illumina, attaching Python: A Revolution in Early Cancer Detection, Dec. 3, 2019)). Grail explained that “[t]his strategy gives Python [Grail] the option to develop products aimed at augmenting and eventually replacing established screening modalities such as spiral CT for lung cancer and mammography for breast cancer while simultaneously driving transformation of the screening paradigm with a pan-cancer product.” (PX2712 (Illumina) at 009 (Email from M. Nguyen, Illumina, to P. Scagnetti, Illumina, attaching Python: A Revolution in Early Cancer Detection, Dec. 3, 2019)).
680. Grail’s former CEO—Mr. Bishop—testified that he does not expect Galleri to compete with either Freenome’s or Guardant’s colorectal cancer screening test. (Bishop (Grail) Tr. 1390-91; 1394).



681. Mr. Bishop explained that Galleri should not be used as a single-cancer blood-based screening test because “[i]t’s being developed with a specific objective and optimized performance attributes to be a multicancer detection test to be used alongside single-cancer detection tests.” (PX7069 (Bishop (Grail) IHT at 145)).

d) Industry Participants Testified That MCED Tests Will Complement Single-cancer Screening Tests

682. Grail’s MCED test developer rivals also do not view NGS-based single-cancer early detection tests as directly competitive with MCED tests. (See, e.g., PX7105 (Getty (Guardant) Dep. at 25-27) (testifying that “a multi-cancer test provides distinct value over a single cancer test”); PX7042 (Gao (Singlera) IHT at 120)).

683. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 187 (*in camera*)).

684. Guardant’s William Getty testified, “if we can offer a physician a test that covers colorectal, breast, lung, pancreatic, you know, so on and so forth, with the check of a pen . . . that would have significant value to the patient to be screened for multiple cancers at one particular time, and also value for the physician who could do so in an efficient fashion.” (PX7105 (Getty (Guardant) Dep. at 23)).

685. Guardant’s Mr. Sood testified, “[I]f I’m going to the doctor’s office to give blood, you know, I want to be screened for as many cancers as possible. So I think eventually that’s where the world will end [up].” (PX7090 (Sood (Guardant) Dep. at 106)).

686. [REDACTED] } (PX7040 (Getty (Guardant) IHT at 151) (*in camera*)).

687. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 187) (*in camera*)).

C. **BROWN SHOE FACTORS SHOW THAT THE RELEVANT PRODUCT MARKET IS MCED TESTS**

1. **MCED Tests Will Have Distinct Pricing and Reimbursement from Other Oncology Tests**

688. Guardant’s Senior VP of Product, Nitin Sood, testified that “screening, to be widely adopted, must be economical, because it addresses such a large population. Whereas . . . tests that may address niches of people, . . . patient population, small groups of patient populations can be more expensive.” (PX7090 (Sood (Guardant) Dep. at 110-11)).

689. [REDACTED] } (See PX7069 (Bishop (Grail) IHT at 149 (in camera))

690. As Illumina’s CEO Francis deSouza testified, [REDACTED] (PX7072 (deSouza (Illumina) IHT at 149) (in camera)).

a) [REDACTED]

691. [REDACTED] } (PX4079 (Grail) at 005 (A revolution in Early Cancer Detection, Jan. 16, 2020) (in camera)).

692. Grail internally performed its own analysis of [REDACTED] (PX4079 (Grail) at 007 (A revolution in Early Cancer Detection,, Jan. 16, 2020) (in camera)).

693. [REDACTED] } (PX4055 (Grail) at 009-010, 023-024 (A Revolution in Early Cancer Detection, Q3 ‘20 BoD Commercial slides) (in camera)).

694. [REDACTED] (PX4450 (Grail) at 009 (in camera)).

695. [REDACTED] (PX4170 (Grail) at 009 ( [REDACTED] ) (in camera)).

696. Grail [REDACTED] (PX4456 (Grail) at 013 (in camera)). } [REDACTED] } (PX4456 (Grail) at 013 (in camera)).

697. [REDACTED] } (PX4075 (Grail) at 043 (Email from A. Aravanis, Grail, to M. Young, Grail, regarding “follow up on competition”, Sept. 7, 2019, attaching a PowerPoint presentation titled “Competitive Intelligence,” Aug. 14, 2019) (*in camera*)).

b) MCED Test Developers Also Anticipate Pricing-Based MCED Competition

698. Freenome CEO Mr. Nolan testified that [REDACTED] (Nolan (Freenome) Tr. 2774-75 (*in camera*)).

699. Guardant expects that primary care physicians will choose among MCED test providers based on multiple factors. (Getty (Guardant) Tr. 2670).

700. [REDACTED] (Getty (Guardant) Tr. 2671; *see* PX7105 (Getty (Guardant) Dep. at 181) (explaining that its goal is “to have a test that has strong access, so low out-of-pocket cost for patients”); PX7051 (Lengauer (Third Rock Ventures) IHT at 178-80) (*in camera*); [REDACTED] }; PX7042 (Gao (Singlera) IHT at 99) (explaining that the price of the MCED test should be less than \$1,000 for market acceptance in the United States)).

701. In addition to price, Mr. Getty testified that primary care physicians choosing among multiple screening tests will consider how easy it is for their staff to conduct the test, the performance characteristics of the test, and the number of cancers for which the test screens. (Getty (Guardant) Tr. 2671-72).

702. Singlera also expects to compete with Grail’s Galleri on multiple metrics, including price. (PX7042 (Gao (Singlera) IHT at 99-100)).

703. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 247-248) (*in camera*); PX7058 (Conroy (Exact) IHT at 111-113) (*in camera*)).

704. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 83-84) (*in camera*)); *see* PX8654 (Helio) (Email exchange between J. Li, Helio, D. Taggart, Helio, et al., Mar. 9, 2021) (discussing Grail’s announcement of a \$600-900 target price)).

## 2. MCED Tests Target Distinct Customers from Other Oncology Tests

705. [REDACTED] } (Della Porta (Grail) Tr. 514 (*in camera*)).
706. Patients that would use MCED tests are different from patients that use therapy selection tests. (Getty (Guardant) Tr. 2502). There are about 700,000 to one million patients that have advanced-stage disease who might use a therapy selection test, compared to 100 to 120 million patients who could use an MCED test. (Getty (Guardant) Tr. 2501-02).
707. [REDACTED] } (Rabinowitz (Natera) Tr. 353-54 (*in camera*)).
708. Average-risk patients are generally defined as “45 and up.” (PX7105, Getty (Guardant) Dep. at 18).
709. [REDACTED] } (PX7040 (Getty (Guardant) IHT at 31-32)); *see also* (PX4082 (Grail) at 008-009 (Email attaching “Grail S-1\_A #1 As Filed,” Sept. 17, 2020)); PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*)); PX7100 (Chudova (Guardant) Dep. at 15-16)); PX7094 (Nolan (Freenome) Dep. at 252-53) (*in camera*)).
710. Because MCED tests are targeted towards patients who do not have symptoms of, and have not been treated for, cancer, [REDACTED] (PX7058 (Conroy (Exact) IHT at 103-04) (*in camera*)).
711. [REDACTED] (PX4267 (Grail) at 008) (*in camera*)). (PX4133 (Grail) at 016 (Email from H. Bishop, Grail, to F. deSouza, Illumina, attaching “Early Cancer Detection Investor Presentation,” Aug. 2020) (explaining “Galleri is designed to be easy to use in primary care”)); PX2712 (Illumina) at 019 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, attaching Python A Revolution in Early Cancer Detection, Dec. 3, 2019) (“While the oncology community will be critical to impressions of the utility and accuracy of our test, it is the general practitioner who orders routine screening tests like PSA and mammograms.”)).
712. [REDACTED] (PX4475 (Grail) at 033) (*in camera*)).

713. [REDACTED] } (Ofman (Grail) Tr. 3417 (*in camera*)).
714. [REDACTED] (Bishop (Grail) Tr. 1322; *see* Lengauer (Third Rock Ventures) Tr. 190 (*in camera*) (testifying that [REDACTED] [REDACTED] }; PX7091 (Lengauer (Third Rock Ventures) Dep. at 148-50) (*in camera*)) ([REDACTED] })).
715. [REDACTED] } (PX4075 (Grail) at 026 (Email from A. Aravanis, Grail, to M Young, Grail, et al., attaching Competitive Intelligence An Overview, Aug. 14, 2019) (*in camera*)) [REDACTED] (PX4075 (Grail) at 027 (Email from A. Aravanis, Grail, to M Young, Grail, et al., attaching Competitive Intelligence An Overview, Aug. 14, 2019) (*in camera*)).
716. For example, Guardant anticipates that the primary customer for MCED tests would be primary care physicians. (Getty (Guardant) Tr. 2502).
717. [REDACTED] (Nolan (Freenome) Tr. 2769-70) (*in camera*)).

**3. Both Blood-Based and Non-Blood Based Single-Cancer Screening Tests Have Different Customers**

718. As set forth above in Sections III.B.1. (USPSTF Cancer Screening Methods are Complementary to MCED Tests) and III.B.2. (Other Non-USPSTF Single-Cancer Blood-Based Tests are Not Close Substitutes for MCED Tests), the existing single-cancer screening framework complements MCED tests, resulting in different customer bases.
719. Current screening tests are recommended for a different subset of the population than MCED tests will be. (*Compare* PX4303 (Grail) (Project Galileo Industry Report Pre-Read Presentation, May 7, 2018) (explaining the USPSTF guidelines) (*in camera*) with PX4082 (Grail) at 008-009 (Email attaching Grail 2020 S-1/Amended, Sept. 2020) (explaining that the Galleri test will be targeted for asymptomatic patients at their annual check-up)).
720. “The Galleri test is intended to be complementary to, and not a replacement of, U.S. guideline-recommended cancer screening.” (PX0063 at 001 (Grail’s Galleri website)).
721. MCED tests target customers who want to test for a multitude of cancers versus single-cancer tests that focuses on customers who want to test for a particular type of cancer.

(Ofman Tr. 3312) (“[W]hen you order Galleri as a physician, you’re not suspecting any particular type of cancer. That’s why you order Galleri.”).

722. [REDACTED] (PX4303 (Grail) (Project Galileo Industry Report Pre-Read Presentation, May 7, 2018) (*in camera*)).

723. [REDACTED] (PX4303 (Grail) (Project Galileo Industry Report Pre-Read Presentation, May 7, 2018) (*in camera*)).

724. [REDACTED] (PX4303 (Grail) (Project Galileo Industry Report Pre-Read Presentation, May 7, 2018) (*in camera*)).

725. [REDACTED] ((PX4303 (Grail) (Project Galileo Industry Report Pre-Read Presentation, May 7, 2018) (*in camera*)).

**4. DAC, Therapy Selection, and MRD Have Different Customers**

726. DAC tests, in contrast, are intended for “symptomatic patients with a suspicion of cancer.” (PX4082 (Grail) at 013 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

727. DAC tests will be “targeted “to oncologists and specialists.” (PX4116 (Grail) (Email from M. Podoll, Morgan Stanley, to A. Freidin, Grail et al., attaching IPO Roadshow Video Outline: Project Galileo, Aug. 2020)).

728. Patients that would use MCED tests are also different from patients that use therapy selection tests. (Getty (Guardant) Tr. 2502).

729. [REDACTED] (See Getty (Guardant) Tr. 2503; *see also* PX7080 (Silvis (Tempus) Dep. at 31-33); PX8474 (Guardant) at 007 [REDACTED] (*in camera*); PX7040 (Getty (Guardant) IHT at 68-69); PX7068 (Perettie (FMI-Roche) IHT at 32 (*in camera*)).

730. [REDACTED] (See PX7068 (Perettie (FMI-Roche) IHT at 32 (*in camera*)).

731. [REDACTED] } (See PX7121 (Otte (Freenome) Dep. at 181-82 (*in camera*) ( [REDACTED] }); PX8474 (Guardant) at 007 [REDACTED] (*in camera*)).

**5. The Parties Recognize That MCED Testing Is Its Own Relevant Market**

a) Illumina and Grail Refer to the MCED Industry, MCED Segment, and MCED Space

732. Grail publicly describes Galleri as an MCED test. (Bishop (Grail) Tr. 1319).

733. Grail refers to its Galleri test as an MCED test on its corporate website. (Bishop (Grail) Tr. 1319).

734. As shown in PX0063, Grail’s website prominently refers to Galleri as a “Multi-cancer early detection test.” (PX0063 at 001 (Grail, Galleri, Apr. 29, 2021)).

735. [REDACTED]

[REDACTED]

{ }

(PX4015 (Grail) at 053 (Grail, Board of Directors Meeting, September 10, 2020) (*in camera*)).

736. Grail identifies itself in its documents as [REDACTED]

(PX4048 (Grail) at 003-004 (*in camera*))

PX4037 (Grail) at 008 (*in camera*); PX4075 (Grail)

at 005 (Grail, Competitive Intelligence, Aug. 14, 2019) (*in camera*); [REDACTED]

[REDACTED] } This is consistent with testimony from Grail’s executives. (See (PX7092 (Ofman (Grail) Dep. at 92); PX7083 (Bishop (Grail) Dep. at 23-24); PX7103 (Jamshidi (Grail) Dep. at 38-39)).

737. A May 2018 Grail document analyzes [REDACTED] (PX4295 (Grail) at 004 (Project Galileo – industry report, May 7, 2018) (*in camera*)).

738. Jeff Huber’s—Grail’s former CEO—reaction to Thrive’s launch was that it was “good to have a ‘market’ instead of a single company, and now we have a market. It’ll also mean there will be others pushing the rock up the hill for reimbursement – which is a very good thing.” (PX4121 (Grail) at 001 (Email from Jeff Huber to the Grail Board of Directors, May 30, 2018)).

739. Hans Bishop—Grail’s former CEO—also acknowledged that Exact is also in the “multicancer early detection space.” (PX7069 (Bishop (Grail) IHT at 153)).

740. Mr. Bishop expects that “other multicancer early detection tests will eventually [be] launched in the market.” (PX7069 (Bishop (Grail) IHT at 163)).

741. Grail’s [REDACTED] (PX4456 (Grail) at 013 [REDACTED] (*in camera*)).

742. [REDACTED] } (PX4284 (Grail) at 020 (Email from J. Ayers to M. Burns regarding GRAIL: First draft corporate communications plan attaching “GRAIL Corporate Comms Plan 5 19 2020 FINAL) (*in camera*)).

743. [REDACTED] } (PX4615 (Grail) at 070 [REDACTED] (*in camera*)).

744. Illumina documents presented to its Board of Directors regarding this transaction also discuss a market for MCED tests. [REDACTED] (PX5030 (Illumina) at 006 [REDACTED] (*in camera*)); see (PX7059, Scagnetti (Illumina) IHT at 63-64 (*in camera*)) ([REDACTED] (PX5030 (Illumina) at 009 (*in camera*)).

745. Illumina’s 2021-2025 Strategic Plan [REDACTED]



[REDACTED] (PX2169 (Illumina) at 048 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

b) [REDACTED]

746. [REDACTED]

747. [REDACTED] } (Berry (Illumina) Tr. 751-53) (*in camera*).  
[REDACTED] } (Berry (Illumina) Tr. 753) (*in camera*).

748. [REDACTED] } (Berry (Illumina) Tr. 938 (*in camera*)). }  
[REDACTED] } (Berry (Illumina) Tr. 938 (*in camera*)).

749. [REDACTED] } (Berry (Illumina) Tr. 753-54) (*in camera*).

750. [REDACTED] (Bishop (Grail) Tr. 1497-98 (*in camera*); PX4063 (Grail) at 001 (Email from Megan Hall, Grail, to Executive Team, Grail, et al., Feb. 2, 2021)).

751. [REDACTED] (Bishop (Grail) Tr. 1498-99 (*in camera*); PX4063 (Grail) at 001 (Email from Megan Hall, Grail, to Executive Team, Grail, et al., Feb. 2, 2021)).

752. [REDACTED]

753. [REDACTED] (PX4259 (Grail) at 001 (Email from C. Della Porta, Grail, to J. Ofman, Grail, copying A. Aravanis, Grail, H. Bishop, Grail, J. Owens, Grail, and V. Demas, Grail, Jul. 22, 2019) (*in camera*)).



c) Illumina and Grail Track Research and Development Efforts of MCED Test Developers

763. Illumina tracks investment activity in MCED testing companies. (deSouza (Illumina) Tr. 2392).
764. Grail’s R&D team tracks the research and development efforts of other companies that are developing MCED tests. (Della Porta (Grail) Tr. 583). [REDACTED] (PX4037 (Grail) at 008-10 [REDACTED] (in camera)).
765. [REDACTED] } (PX4075 (Grail) at 009 (Email attaching Competitive Intelligence: An Overview, Aug. 14, 2019) (in camera)).
766. [REDACTED] } (PX4287 (Grail) at 013-14 [REDACTED] (in camera)). [REDACTED] } (PX4287 (Grail) at 022-042, 045-049 [REDACTED] (in camera)).
767. In Grail’s AACR Conference Report, dated May 5, 2021, Grail’s Medical Affairs and R&D and Bioinformatics teams wrote: “MCED evolving into highly competitive landscape, though many seem to be starting with one cancer type, with intent to add more.” (PX4616 (Grail) at 017 (Grail, AACR Conference Report, May 5, 2021)).
768. The same Grail AACR Conference Report identifies Exact/Thrive as Grail’s “most significant competitor in MCED space.” PX4616 (Grail) at 030 (Grail, AACR Conference Report, May 5, 2021)).
769. [REDACTED] (Ofman (Grail) Tr. 3421-22 (in camera)).
770. Grail’s 2021 AACR Conference Report (PX4616) credits 27 Grail employees: 17 members of Grail’s Medical Affairs team and ten members of Grail’s bioinformatics and R&D teams. (PX4616 (Grail) at 135 (Grail, AACR Conference Report, May 5, 2021)).
771. [REDACTED] } (Della Porta (Grail) Tr. 582-83). [REDACTED] } (PX4037 (Grail) at 008-010 [REDACTED]

- [REDACTED] (in camera)).
772. [REDACTED] (PX4266 (Grail) at 013 [REDACTED] (in camera)).
773. Dr. Katz, Respondents’ expert, agreed that Grail has a process in place “that identi[fies] technologies and competitors whose approaches are worth evaluating for future iterations of Grail’s product.” (RX6004 (Katz Trial Dep. at 105).
774. Specifically, Dr. Katz, testified that firms that are developing MCED tests have identified other MCED developers as competitors. (RX6004 (Katz Trial Dep. at 104)).
775. Dr. Katz also testified that firms developing MCED tests have assessed their rivals’ product features for their MCED tests. (RX6004 (Katz Trial Dep. at 104).
776. Dr. Katz understood that firms in the MCED industry track the science of other firms developing MCED tests. (RX6004 (Katz Trial Dep. at 105).

**6. Industry Participants View MCED Tests as Its Own Relevant Market**

777. As captured below and in Section VI, [REDACTED] (See, e.g., Nolan (Freenome) Tr. 2773-4 (in camera) [REDACTED]; PX8392 (Exact) at 002 (in camera) [REDACTED]; PX7042 (Gao (Singlera) IHT at 102-103) (testifying that Singlera’s PanSeer test is in the pan-cancer market, competing against companies like Grail, Exact, Freenome, and Thrive); PX7053 (Fesko (Natera) IHT at 84) (in camera) [REDACTED]).
778. At trial, MCED test developers referred to their tests as MCED tests. (See, e.g., (Lengauer, Tr. 158-59) (describing CancerSEEK as “a multicancer blood test for the . . . early detection of cancer”); (Chahine (Helio) Tr. 1000) (differentiating Helio’s liver cancer test from its “multicancer test”); (Nolan (Freenome) Tr. 2709) (discussing Freenome’s “multicancer program”)).
779. [REDACTED] (See, e.g., PX8392 (Exact) at 002 (in camera); RX0545 (Guardant) at 010 (in camera) [REDACTED]; PX8324 (Roche) at 003 [REDACTED] (in camera)).

a) [REDACTED]

780. [REDACTED] } (Chahine (Helio) Tr. 1066 (in camera)).

781. [REDACTED] } (Chahine (Helio) Tr. 1066-67 (in camera)).

782. For example, [REDACTED] } (PX8655 (Helio) at 029 (in camera)).

783. [REDACTED] } (Chahine (Helio) Tr. 1067 (in camera)).

784. [REDACTED] } (Chahine (Helio) Tr. 1067 (in camera)).

b) [REDACTED]

785. When describing the CancerSEEK test, former Chief Innovation Officer and Co-Founder of Thrive, Dr. Lengauer, explained that “we call it a multicancer test. That’s in stark contrast to single organs test that only look for one particular organ.” (Lengauer (Third Rock Ventures) Tr. 159-60).

786. Mr. Conroy testified that there is now a nascent market—as Mr. Conroy uses the term as a layperson—in MCED testing since Galleri became available. (Conroy (Exact) Tr. 1738).

787. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 194-95 (in camera)).

788. [REDACTED] } (Conroy (Exact) Tr. 1652 (in camera)).

789. [REDACTED] } (PX8572 (Exact) at 048 (Exact Sciences Innovation & Technology Committee)) (in camera) ([REDACTED] })).

790. [REDACTED] (PX8572 (Exact) at 092 (Exact Sciences Innovation & Technology Committee) (in camera)).

791. [REDACTED] (PX7051  
(Lengauer (Third Rock Ventures) IHT at 177-78) (*in camera*)).

c) [REDACTED]

792. [REDACTED] }  
(Rabinowitz (Natera) Tr. 359 (*in camera*)).

793. [REDACTED] }  
(Rabinowitz (Natera) Tr. 359 (*in camera*)).

794. [REDACTED] } (Rabinowitz  
(Natera) Tr. 360 (*in camera*)).

795. [REDACTED] } (Rabinowitz (Natera) Tr. 360 (*in camera*)).

d) Guardant Has Identified MCED Test Developers as Competitors in Its Market

796. Guardant estimates the potential size of the MCED market in terms of revenue as over \$50 billion. (Getty (Guardant) Tr. 2503).

797. Guardant monitors Grail because of its funding and the advanced state of its technology. (Getty (Guardant) Tr. 2504).

798. Guardant is “really focused” on Grail as a competitor. (Getty (Guardant) Tr. 2505).

799. Guardant monitors Exact as a competitor because of Exact’s funding and the advanced state of its technology. (Getty (Guardant) Tr. 2504).

800. Guardant also views Grail, Natera, Exact, and Freenome as competitors in MCED test development. (Getty (Guardant) Tr. 2687-88) (referring to PX0060 (Guardant) at 014 (Guardant 10-K for fiscal year ending Dec. 31, 2020)).

e) [REDACTED]

801. [REDACTED] }  
(PX7050, Nolan (Freenome) IHT at 137, 251-52 (*in camera*)).

802. Freenome CEO, Michael Nolan, testified at trial that [REDACTED] [REDACTED] } (Nolan (Freenome) Tr. 2774 (*in camera*)).

803. [REDACTED] [REDACTED] } (Nolan (Freenome) Tr. 2772-73 (*in camera*)).

804. Freenome views Grail as a competitor in offering MCED tests. (Nolan (Freenome) Tr. 2727).

805. Freenome CEO, Michael Nolan, testified that because Grail’s MCED test is [REDACTED] [REDACTED] (Nolan (Freenome) Tr. 2774 (*in camera*)).

806. Mr. Nolan testified that [REDACTED] [REDACTED] } (Nolan (Freenome) Tr. 2774-75 (*in camera*)).

f) [REDACTED] [REDACTED]

807. [REDACTED] [REDACTED] (PX8324 (Roche) at 003 (*in camera*)).

808. Cindy Perettie from Foundation Medicine is aware that Grail, Thrive, Exact Sciences, Freenome, and Natera are “developing NGS-based early cancer detection tests.” (PX7068 (Perettie IHT at 54-55)).

**7. Legislators, Regulators, and Others Discuss an [REDACTED] Market**

809. The U.S. House of Representatives and Senate introduced the Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020, which states that MCED tests “can complement the covered early detection tests,” rather than replace them. (H.R. 8845 (116<sup>th</sup> Congress, 2d Session), Sec. 2(a)(7)). (RX2588 (Illumina) (Reps. Sewell, Arrington, Ruiz, and Hudson Introduce Bipartisan Legislation to Remove Barriers to Innovative Multi-Cancer Screening Technology for Medicare Beneficiaries, Dec. 3, 2020, <https://sewell.house.gov/media-center/press-releases/rep-sewell-arrington-ruiz-and-hudson-introduce-bipartisan-legislation>, last visited Apr. 6, 2022) (stating “these new tools will complement, not replace, existing screenings”)).

810. [REDACTED] [REDACTED] (RX2588 (Illumina) (Reps. Sewell, Arrington, Ruiz, and Hudson Introduce Bipartisan Legislation to Remove Barriers to

Innovative Multi-Cancer Screening Technology for Medicare Beneficiaries, Dec. 3, 2020, <https://sewell.house.gov/media-center/press-releases/rebs-sewell-arrington-ruiz-and-hudson-introduce-bipartisan-legislation>, last visited Apr. 6, 2022) (stating “these new tools will complement, not replace, existing screenings”). *See also* (Bishop (Grail) Tr. 1323-24); (Ofman (Grail) Tr. 3356 (*in camera*)).

811.

[REDACTED] } (Ofman (Grail) Tr. 3353 (*in camera*)).

812.

[REDACTED] (Ofman (Grail) Tr. 3356 (*in camera*)).

813. As noted above at Complaint Counsel’s Proposed Findings of Fact ¶¶ 587, 590-591, Grail has lobbied Congress to pass legislation to enable Medicare’s coverage MCED tests.

814. The U.S. House of Representatives and Senate introduced the “Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020,” which states that MCED tests “can complement the covered early detection tests,” rather than replace them. (H.R. 8845 (116th Congress, 2d Session), Sec. 2(a)(7)). (RX2588 (Illumina) (Reps. Sewell, Arrington, Ruiz, and Hudson Introduce Bipartisan Legislation to Remove Barriers to Innovative Multi-Cancer Screening Technology for Medicare Beneficiaries, Dec. 3, 2020, <https://sewell.house.gov/media-center/press-releases/rebs-sewell-arrington-ruiz-and-hudson-introduce-bipartisan-legislation>, last visited Apr. 6, 2022) (stating “these new tools will complement, not replace, existing screenings”)).

815. The Press Release announcing the legislation specifies tests that “detect multiple types of cancer before systems develop.” (RX2588 (Illumina) (Reps. Sewell, Arrington, Ruiz, and Hudson Introduce Bipartisan Legislation to Remove Barriers to Innovative Multi-Cancer Screening Technology for Medicare Beneficiaries, Dec. 3, 2020, <https://sewell.house.gov/media-center/press-releases/rebs-sewell-arrington-ruiz-and-hudson-introduce-bipartisan-legislation>, last visited Apr. 6, 2022) (“The bipartisan legislation recognizes emerging advances in our nation’s fight against cancer by ensuring Medicare coverage for new, innovative tests that detect multiple types of cancer before symptoms develop.”)).

816. The text of the “Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020” defines “Multi-Cancer Early Detection Screening Tests” as “any of the following tests, approved or cleared by the Food and Drug Administration, furnished to an individual for the purpose of early detection of cancer across many cancer types (as categories in the Annual Report to the Nation on the Status of Cancer issued by the National Cancer Institute): (1) A genomic sequencing blood or blood product test that includes the analysis of cell-free nucleic acids. (2) Such other equivalent tests (which are based on urine or other



sample of biological material) as the Secretary determine appropriate.” (RX3602 (H.R.1946 - To Amend Title XVIII of the Social Security Act to Provide for Medicare Coverage of Multi-Cancer Early Detection Screening Tests)).

817. The “Purpose” section of the “Medicare Multi-Cancer Early Detection Screening Coverage Act of 2020” says that “Several innovative private and academic efforts are engaged in research, including advanced clinical trial to develop multi-cancer early detection blood-based tests. Published data indicate that these tests can screen for many cancers at the same time, including rare cancers, with one example currently able to screen for more than 50 cancers.” ((RX3602 (H.R.1946 - To Amend Title XVIII of the Social Security Act to Provide for Medicare Coverage of Multi-Cancer Early Detection Screening Tests))).
818. Guardant’s Mr. Getty testified at trial that “there are benchmarks that are out there that suggest” the uses for which third-party payers will cover MCED tests. (Getty (Guardant) Tr. 2662-63).
819. [REDACTED] (Strom (Morgan Stanley) Tr. at 3567 (*in camera*)).
820. Cowen—a financial services firm—identified multi-cancer screening tests target at asymptomatic patients as its own market and assessed that it would have approximately a \$5 to \$50 billion target addressable market in its report on liquid biopsy. (PX2752 (Illumina) at 007 (“The Liquid Biopsy Report: Early Detection of a Huge Opportunity)). Cowen’s market assessment separately addressed single cancer tests, tests targeting high risk patients, and tests with a non-screening function. (PX2752 (Illumina) (“The Liquid Biopsy Report: Early Detection of a Huge Opportunity”).
821. Investors have also identified an MCED market and noted that Galleri test competes with other MCED test developers. (PX2138 (Illumina) at 008 (JPMorgan Investor Report “Searching for the (Un) Holy Grail: Deal Brings More Dilution than Test Sensitivity . . . Downgrading to Neutral, PT to \$280”) (“To address concerns around potential cannibalization into ILMN’s existing customers that compete with Grail (GH. Freenome, Thrive, etc.”)); PX2138 (Illumina) at 025 (Wolfe Research “Betting The Farm) (recognizing that Guardant Health, Freenome, Exact, and Thrive are all posed to compete with GRAIL)).

**D. THE HYPOTHETICAL MONOPOLIST TESTS SHOWS MCED TESTS ARE A RELEVANT PRODUCT MARKET**

822. Dr. Scott Morton concluded that the relevant product market is MCED tests. (PX7138 (Scott Morton Trial Dep. at 38)).
823. [REDACTED] (PX7138 (Scott Morton Trial Dep. at 40-43); PX6090 (Scott Morton Report) ¶ 149 (*in camera*)).

824. As described more fully in her expert report, Dr. Scott Morton found that “a hypothetical monopolist of all MCED products would likely be able to profitably impose a SSNIP above the MCED price that would prevail if there were multiple MCED rivals or profitably implement a significant reduction in product quality or availability.” (PX7138 (Scott Morton Trial Dep. at 40-43); PX6090 (Scott Morton Report) ¶ 149 (*in camera*)).

825. [REDACTED] } (PX6090 (Scott Morton Report) ¶ 146 (*in camera*)).

826. [REDACTED] } (PX6090 (Scott Morton Report) ¶ 146 (*in camera*)).

827. Dr. Scott Morton testified that a quantitative hypothetical monopolist test is not required to define a product market. (PX7138 (Scott Morton Trial Dep. at 42-43)).

828. Respondents’ economic expert admits that switching data and customer survey data is not necessary to define a relevant product market. (RX6004 (Katz Trial Dep. 99); *see also* PX0338 at 011-012, (*Horizontal Merger Guidelines* § 4.1.3, dated Aug. 19, 2010) (“Even when the evidence necessary to perform the hypothetical monopolist test quantitatively is not available, the conceptual framework of the test provides a useful methodological tool for gathering and analyzing evidence pertinent to customer substitution and to market definition. The Agencies follow the hypothetical monopolist test to the extent possible given the available evidence, bearing in mind that the ultimate goal of market definition is to help determine whether the merger may substantially lessen competition.”)).

829. [REDACTED] (See PX6090 (Scott Morton Report) ¶ 139 (*in camera*)).

830. [REDACTED] (See RX3865 (Guerin-Calvert Rebuttal Report) (*in camera*); PX6105 (Katz Rebuttal Report) (*in camera*); RX3870 (Rock Rebuttal Report) (*in camera*); RX3867 (Deverka Rebuttal Report) (*in camera*); RX3864 (Carlton Rebuttal Report) (*in camera*); RX3869 (Cote Rebuttal Report) (*in camera*); PX6097 (Abrams Rebuttal Report) (*in camera*)).

**IV. THE UNITED STATES IS THE RELEVANT GEOGRAPHIC MARKET**

**A. THE UNITED STATES HAS UNIQUE REGULATORY REQUIREMENTS FOR MCED TESTS**

831. In the United States, the Food and Drug Administration (“FDA”) and Centers for Medicare & Medicaid Services (“CMS”) (via the Clinical Laboratory Improvement Amendments of

1988 (“CLIA”)) regulate MCED tests. (PX0043 (Grail) at 115, 132 (Grail 2020 Form S-1)).

832. Dr. Chudova testified that the U.S. regulatory framework requires that the technology underlying an NGS platform be available for use in the U.S. for Guardant to commercialize its cancer screening test using that NGS platform:

We have -- so we are working as a lab under two potential regulatory landscapes. We either work as a lab-developed test in -- under the CLIA regulations, or we’re working under the FDA approval for a test that we can run in our internal lab. None of these configurations assume that you can -- you can -- you can use a technology that’s not available in the U.S., as far as I can tell from regulatory sort of constraints around this.

(PX7045 (Chudova (Guardant) IHT at 52-53)).

833. Dr. Chahine explained at trial that there are “two major options for bringing a diagnostic test to market” in the United States. (Chahine (Helio) Tr. 1027-28). “The first is to go through [the] FDA process ... [and] the second way you can launch a product in the United States ... is under ... CLIA ... the Clinical Laboratory Improvement Act [which is] run by a different government agency.” (Chahine (Helio) Tr. 1028).

834.  (Rabinowitz (Natera) Tr. 382 (*in camera*)).

**1. Centers for Medicare & Medicaid Services Oversees Laboratory Developed Tests**

835. A laboratory-developed test (“LDT”) must meet Clinical Laboratory Improvement Amendments (“CLIA”) and College of American Pathologists (“CAP”) guidelines, which are clinical lab guidelines. (Goswami (Illumina) Tr. 3185-86).
836. An MCED test may be sold in the United States as a laboratory-developed test (“LDT”) before the test has received Premarket Approval from the FDA if it is developed pursuant to CLIA/CAP guidelines (Goswami (Illumina) Tr. 3222).
837. To be offered to U.S. patients, LDTs must be performed in CLIA-certified labs. (Febbo (Illumina) Tr. 4320).
838. Grail described CLIA requirements to its investors explaining “CLIA is a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis prevention, or treatment of disease ....” (PX0043 (Grail) at 043 (Grail 2020 Form S-1)).
839. Grail represented to investors that CLIA certification requires laboratories to “mandate specific standards in the areas of personnel qualifications, administration, participation in

proficiency testing, test management, and quality assurance. (PX0043 (Grail) at 043 (Grail 2020 Form S-1)).

- 840. Grail represented to investors that failure of Grail or its partners to comply with CLIA regulations could result in “prevent[ion] from performing our tests or .... disruption[] to our business. (PX0043 (Grail) at 043 (Grail 2020 Form S-1)).
- 841. The Centers for Medicare & Medicaid Services (“CMS”) certifies laboratory compliance with CLIA. (Ofman (Grail) Tr. 3317-18).
- 842. Dr. Chahine explained that CLIA evaluates and set standards for laboratory developed tests that ensures the “laboratory quality, robustness, and accuracy of the test.” (Chahine (Helio) Tr. 1029).
- 843. Dr. Ofman testified that an LDT is also subject to FDA oversight of the representations that company makes about the LDT test stating a company offering an LDT “still need[s] to follow all the major guidances from the FDA about supportable claims and having evidence to support your claims ....” (Ofman (Grail) Tr. 3317-18).

**2. The FDA Will Classify MCED Tests as Class III Medical Devices Requiring Pre-Market Approval**

- 844. Grail represented to investors that it anticipates that the FDA will classify Galleri as a Class III device and require a PMA approval. (PX0043 (Grail) at 129 (Grail 2020 Form S-1)). Grail represented to investors that generally Class III medical devices require PMA approval by the FDA before they can be marketed. (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
- 845. Grail represented to investors that the FDA looks at a product’s intended use when classifying, reviewing, and approving a Class III device, and the “FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s).” (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
- 846. Grail represented to investors that obtaining PMA approval involves “complete analytical and clinical performance data and also information about the device and its components regarding, among other things, device design, manufacturing and labeling.” (PX4082 (Grail) at 135 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
- 847. Dr. Ofman testified that Grail anticipates the FDA will require MCED tests to obtain Premarket Approval (“PMA”) for FDA approval. (Ofman (Grail) Tr. 3319).
- 848. Illumina’s Dr. Febbo testified that Illumina anticipates that the FDA will classify MCED tests as Class III (high-risk) medical devices. (Febbo (Illumina) Tr. 4445); PX7099 (Febbo (Illumina) Dep. at 83-84)).

- 849. Dr. Rabinowitz testified that Natera anticipates that the FDA is likely to require a PMA approval for any cancer test for people who are asymptomatic. (Rabinowitz (Natera) Tr. 302-03).
- 850. Dr. Gao testified that based upon a meeting with the FDA, the FDA classifies MCED tests as a Class III high risk device and will require MCED tests to obtain a PMA for FDA approval. (Gao (Singlera) Tr. 2872-73).

**B. COMMERCIALIZATION OF AN MCED TEST IN THE UNITED STATES WILL REQUIRE FDA APPROVAL BECAUSE OF U.S. PAYER REQUIREMENTS**

**1. CMS Will Not Reimburse for an MCED Test Without FDA Approval**

- 851. Illumina’s CEO Francis DeSouza testified that FDA approval is necessary for federal CMS coverage. (DeSouza (Illumina) Tr. 2414).
- 852. Dr. Ofman testified that “in the U.S. ... we don’t expect that we’ll be able to get Medicare reimbursement without FDA approval. ...” (Ofman (Grail) Tr. 3319-20).
- 853. Dr. Ofman testified that Grail’s “assumption[] and our plan is that get broad Medicare coverage, we will need a PMA approval.” (PX7092 (Ofman (Grail) Dep. at 175)).
- 854. Dr. Chahine testified that CMS issued guidance “stating that it would require FDA approval for reimbursement under CMS” for early cancer detection. (Chahine (Helio) Tr. 1029).
- 855. Mr. Conroy testified that FDA approval is necessary to obtain CMS payment for Medicare patients. (Conroy (Exact) Tr. 1734).
- 856. [REDACTED] } (Conroy (Exact) Tr. 1560-61) (*in camera*); PX7058 (Conroy (Exact/Thrive) IHT at 87) (*in camera*)).
- 857. [REDACTED] (PX4172 (Grail) at 059 (Grail, Board of Directors Meeting, Nov. 21, 2019) (*in camera*)).
- 858. Illumina admits that “it is unlikely that Galleri will obtain Medicare coverage without FDA premarket approval.” (PX6060 (Illumina) at 023 (Illumina’s Responses & Objections to FTC’s First Set of Interrogatories)).
- 859. An investor report about liquid biopsy markets states that it “is clear that CMS reimbursement [for asymptomatic cancer screening tests] will require FDA approval . . . .” (PX2752 (Illumina) at 020 (“The Liquid Biopsy Report: Early Detection of a Huge Opportunity”)).
- 860. Medicare coverage will be particularly important for MCED test reimbursement because “many other U.S. payors look to the Medicare policies as a benchmark and model for their

own.” (PX0043 at 139 (Grail 2020 Form S-1); *see also* PX9090 (Roche) at 019 (Cowen, The Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sep. 18, 2020) (“[P]ractically speaking, FDA approval is (at a minimum) very important to driving reimbursement – both from CMS . . . and commercial payers”)); PX4035 (Grail) at 039 (PiperJaffray, The 2015 Liquid Biopsy Report) (stating that “our payer diligence suggests the community does view FDA approval as an incremental supportive layer for payment” for liquid biopsy tests)).

**2. FDA Approval Is Also Important to Obtaining Broad Commercial Reimbursement in the United States**

- 861. Grail’s CEO agreed in trial testimony that FDA approval will likely be a prerequisite for getting broad-based reimbursement for Galleri. (Bishop (Grail) Tr. 1343-44).
- 862. Dr. Ofman testified that Grail “does not expect that large U.S. payers are going to provide coverage for the test without FDA approval.” (Ofman (Grail) Tr. 3319-20).
- 863. Illumina’s Dr. Aravanis testified that “FDA approval will help [Grail] with reimbursement and adoption of [Galleri].” (Aravanis Illumina) Tr. 1894).
- 864. [REDACTED] (PX4004 (Grail) at 001 (Email from R. Currie, Illumina, to Executive Leadership Team, Illumina, Aug. 27, 2020) (*in camera*)).
- 865. Grail represented to investors in its Form S-1 that Medicare coverage through CMS is important not only in its own right, but also because “many other U.S. payors look to the Medicare policies as a benchmark and model for their own.” (PX0043 (Grail) at 139 (Grail 2020 Form S-1)).
- 866. Exact Sciences Mr. Conroy testified that obtaining coverage from commercial payers without FDA approval is improbable. (Conroy (Exact) Tr. 1734).
- 867. Mr. Conroy testified [REDACTED] } (PX7058 (Conroy (Exact) IHT at 140-41) (*in camera*)).
- 868. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 88) (*in camera*)).
- 869. [REDACTED] (Getty Guardant) Tr. 2530 (*in camera*)).

870. [REDACTED] (PX7055 (Otte (Freenome) IHT at 35) (*in camera*)).

**3. Obtaining FDA Approval and U.S. Payer Coverage Is Critical for Commercial Adoption of MCEs in the United States**

871. Grail’s CEO testified at trial that FDA approval is “very necessary for getting American citizens access to our test.” (Bishop (Grail) Tr. 1368).

872. Grail represented to investors in its Form S-1, “Medicare is the single largest healthcare payor in the United States, and a particularly significant payor for many cancer-related laboratory services given the demographics of the Medicare population, a large portion of which includes elderly individuals.” (PX0043 at 139 (Grail 2020 Form S-1)).

873. Dr. Ofman testified that “getting PMA approval is going to be critically important for Galleri to get the kind of broad-based coverage and reimbursement that we ultimately want if we really want to make a dent in public health’s cancer crisis.” (PX7092 (Ofman (Grail) Dep. at 176)).

874. [REDACTED] (PX5024 (Illumina) at 024 (Board of Directors M&A Landscape, Apr. 28, 2020) (*in camera*)).

875. Illumina admits that “[t]o make Galleri broadly available in the U.S., it is essential that Galleri obtain coverage from both Medicare and private insurers.” (PX6060 (Illumina Responses & Objections to FTC First Set of Interrogatories) at 023 (Interrogatory No. 3)).

876. An investor report about liquid biopsy markets states that “practically speaking, FDA approval is (at a minimum) very important to driving reimbursement – both from CMS (the biggest payer given many people targeted are Medicare covered) and commercial payers.” (PX2752 (Illumina) at 020 (The Liquid Biopsy Report: Early Detection of a Huge Opportunity, Sept. 18, 2020)).

877. [REDACTED] (RX3864 (Carlton Rebuttal Report) ¶¶ 13, 115 (*in camera*)).

**C. RESPONDENTS RECOGNIZE THE UNITED STATES AS A DISTINCT MARKET**

878. Grail’s Form S-1 filing references a United States-specific “early detection market.” (PX0043 at 005-007 (Grail 2020 Form S-1)).

879. [REDACTED]

[REDACTED] (PX5027 (Illumina) at 015 [REDACTED] (*in camera*)).

880. Illumina admits that requirements to commercialize medical devices in various “international markets” are distinct from the United States and require a “country-by-country process of commercializing” medical devices in previous court filings related to the transaction. (PX6060 (Illumina Responses & Objections to FTC First Set of Interrogatories) at 030-31 (Interrogatory No. 3)).

881. [REDACTED] } (See PX2553 (Illumina) at 145 (Liquid Biopsy Market Landscape Analysis, Oct. 27, 2016) (*in camera*)).

882. [REDACTED] } (See PX2553 (Illumina) at 148 (Liquid Biopsy Market Landscape Analysis, Oct. 27, 2016) (*in camera*)).

883. Grail’s CEO, Hans Bishop, testified that “PMA approval with [the] FDA . . . [provides] American citizens access to our test” and that Grail will “have to go through equivalent processes all around the world to get patients outside of the United States access to our technology.” (Bishop (Grail) Tr. 1368).

884. [REDACTED] (PX6090 (Scott Morton Report) ¶ 150 (*in camera*)).

885. Respondent’s economic expert, Dr. Carlton, does not dispute Dr. Scott Morton’s opinion that the United States is the relevant geographic market to analyze the proposed transaction. (PX7134 (Carlton Dep. at 112-114)).

**V. ILLUMINA NGS IS A NECESSARY INPUT TO MGED TESTS**

**A. NEXT GENERATION SEQUENCING OVERVIEW**

**1. Next Generation Sequencing Determines the Order of Nucleotides in DNA Molecules**

886. Next-generation sequencing (“NGS”) is a method of DNA sequencing, the process of determining the order of nucleotides (A, C, G, or T) in a DNA molecule. (RX3333 at 007 (Illumina 2020 Form 10-K)).

887. Illumina’s website summarizes the NGS process: “The basic next-generation sequencing process involves fragmenting DNA/RNA into multiple pieces, adding adapters, sequencing the libraries, and reassembling them to form a genomic sequence. In principle, the concept is similar to capillary electrophoresis. The critical difference is that NGS sequences



millions of fragments in a massively parallel fashion, improving speed and accuracy while reducing the cost of sequencing.” (PX0113 at 002 (A Beginner’s Guide to NGS)).

- 888. “The way [DNA sequencing] works at a high level is you prepare the DNA,” and perform library preparations “where you take the DNA that you’ve extracted from the sample” and prepare it. (Rabinowitz (Natera) Tr. 304, 307-08).
- 889. “[O]nce the DNA is hybridized onto the flow cell, a process is then undertaken called sequencing by synthesis, where you will add a particular nucleotide to the reaction, and the DNA that’s attached onto the flow cell will be built up next to a matching fragment of DNA where the nucleotide that is added matches the nucleotide that is on that fragment that is attached to the substrate.” (Rabinowitz (Natera) Tr. 307).
- 890. The DNA is prepared for sequencing by attaching sequencing adapters onto the ends of the DNA fragments to allow the DNA to work with a particular sequencer. (Rabinowitz (Natera) Tr. 307-08).
- 891. “Sequencing is a way of taking many fragments of DNA and telling you exactly what those fragments are made of, in other words, what nucleotides, A, C, T, or G, go into those fragments.” (Rabinowitz (Natera) Tr. 304).
- 892. NGS allowed sequencers to complete a sequencing project that would have cost billions of dollars and take over a decade to complete without NGS in a single day for under a thousand dollars. (See PX0124 at 006-007 (Jon Gertner, *New York Times*, “Genome Sequencing and COVID-19 – How Scientists Are Tracking the Virus,” Mar. 25, 2021)).

**2. Short-Read Versus Long-Read Sequencing**

- 893. The two categories of NGS platforms are (1) short read and (2) long read. (PX8399 (Henry (PacBio) Decl. ¶ 3)).
- 894. [REDACTED] } (PX7045 (Chudova (Guardant) IHT at 44-47) (*in camera*); PX8399 (Henry (PacBio) Decl. ¶¶ 3-4)).
- 895. [REDACTED] (PX8399 (Henry (PacBio) Decl. ¶¶ 3-5) (*in camera*); PX7045 (Chudova (Guardant) IHT at 83-84) (*in camera*)). Illumina’s NGS platforms are considered short-read sequencers. (Berry (Illumina) Tr. 823-24).
- 896. [REDACTED] (See PX7042 (Gao (Singlera) IHT at 65); PX7043 (Gunn (Roche) IHT at 83-84) (*in camera*); PX7045 (Chudova (Guardant) IHT at 44-45); PX7046 (George (Invitae) IHT at 77) (*in camera*)).

897. [REDACTED] (PX7043 (Gunn (Roche) IHT at 72) (*in camera*)).
898. [REDACTED] (PX7055 (Otte (Freenome) IHT at 64-65) (*in camera*)).
899. Former Illumina CFO/COO and current PacBio CEO Christian Henry declared that short-read sequencing provides high read count and low cost per read relative to long-read sequencing. (*See, e.g.*, PX8399 (Henry (PacBio) Decl. ¶¶ 3-4)).
900. Former Illumina CFO/COO and current PacBio CEO Christian Henry declared, “[b]ecause [ctDNA fragments] are typically fewer than 350 base pairs long, Illumina’s short-read NGS platforms are capable of analyzing many ctDNA fragments in their entirety.” (PX8399 (Henry (PacBio) Decl. ¶ 5)).
901. [REDACTED] (PX8399 (Henry (PacBio) Decl. ¶¶ 5, 9–11 (*in camera*))).
902. [REDACTED] } (*See* PX8399 (Henry (PacBio) Decl. ¶ 4; PX7045 (Chudova (Guardant) IHT at 44-47) (*in camera*))).
903. [REDACTED] } (*See, e.g.*, PX7045 (Chudova (Guardant) IHT at 45-48) (*in camera*)).
904. MCED developers do not view the long-read NGS platforms of PacBio or Oxford Nanopore as viable alternatives to Illumina’s short-read NGS platform due to their lower read counts, lower accuracy, and higher costs. (*See infra* Section V.E.3. (“Extremely Inefficient” Long-Read NGS Is Not an Option for MCED)).
905. [REDACTED] } (Chudova (Guardant) Tr. 1221-22) (*in camera*)).
906. [REDACTED] } (PX7045 (Chudova (Guardant) IHT at 47-48) (*in camera*)).
907. Christian Henry, President and CEO of PacBio, a provider of long-read sequencing platforms, declared that “[g]iven the relatively short length of many ctDNA fragments, long-read sequencing does not often present the same technical benefits over short-read sequencing as it does for other sequencing applications” and stated that [REDACTED]

[REDACTED] (PX8399 (Henry (PacBio) Decl. ¶ 5) (*in camera*)).

908. Dr. Vogelstein testified that long-read sequencing technologies “are not applicable to the analysis of plasma DNA,” and he elaborated “the reason is simple to understand: Plasma DNA is not long. Plasma DNA, the average size in a normal individual is 167 base pairs. And in cancers, it’s a bit shorter.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 73-74)).

909. [REDACTED] } (PX7045 (Chudova (Guardant) IHT at 44-47, 48-49) (*in camera*); see PX7042 (Gao (Singlera) IHT at 65) (Long-read sequencing would “cost tens of thousands [of] dollar[s] to do the same job” as a short-read sequencer, so long-read sequencers “are not a viable option for screening test[s].”)).

910. Illumina CEO, Francis deSouza, explained in an investor call that in looking at circulating tumor DNA fragments, “the ability to do very long-read doesn’t offer any incremental value and certainly isn’t worth paying a significant premium in terms of the cost per base.” (PX2544 (Illumina) at 027 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching “JP Morgan Life Sciences CEO Conference Call Series” transcript, Sept. 5, 2019)).

911. Dr. Felton does not view long-read NGS platforms such as PacBio or Oxford Nanopore as competitors for oncology applications because the throughput of long-read NGS sequencing is inadequate to meet the needs of oncology testing. (Felton (Thermo Fisher) Tr. 1997-99).

912. Illumina CEO, Francis deSouza, explained to investors that short-read NGS platforms are much more suitable for detecting ctDNA fragments than long-read platforms:

The way we see it is that there are applications that are very well suited for long-read technology, that frankly short-read technology don’t [sic] address and vice versa it’s true as well. But there are markets, our core markets where short-read technologies work exceptionally well and long-read don’t offer any additional values. So let me give you some specifics. If you look at some of our core markets, for example, in NIPT the fragments we’re looking at are 150-ish base pairs. So somewhere between 130 base pairs and maybe up to 200 base pairs long. And so the ability to sequence fragments that are a million base pairs long or a hundred thousand base pairs long is frankly irrelevant, because the fragments are nowhere near that long. And so what customers are looking for is a high-volume sequencer that’s able to cost effectively and accurately read those short fragments. That’s true in circulating tumor DNA fragments in the oncology space as well. And so if you look at the number of our core markets,

the ability to do very long-read doesn't offer any incremental value and certainly isn't worth paying a significant premium in terms of the cost per base.

(PX2544 (Illumina) at 026-027 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching "JP Morgan Life Sciences CEO Conference Call Series" transcript, Sept. 5, 2019)).

913. Dr. Vogelstein testified that long-read sequencing is not suitable for analyzing plasma DNA molecules because "the error rates of long-read sequencers are much too high to effectively analyze the molecules and plasma for [ ] early cancer detection with the number of artifactual mutations outnumbering the expected number of real mutations by many fold." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).
914. Dr. Vogelstein testified that "[l]ong-read sequencers are [ ] unsuited for early detection cfDNA biopsy testing" because "the throughput of long-read sequencers are much lower than the throughput of short-read sequencers." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).

**B. MCED PRESENTS ENORMOUS SCIENTIFIC AND TECHNICAL CHALLENGES**

915. The presence of a cancer signal in an individual's blood at an early stage is "very subtle." (PX7042 (Gao (Singlera) IHT at 39-40)).
916. [REDACTED] (PX4032 (Grail) at 006 ("A Revolution in Early Cancer Detection," Feb. 10, 2020) (*in camera*)).
917. [REDACTED] (PX2013 (Illumina) at 009 ("Cancer Screening," Apr. 28, 2020) (*in camera*)).
918. Thrive's Dr. Lengauer analogized finding cancer cells in a person's blood as looking for the "proverbial needle in the haystack . . . ." (Lengauer (Third Rock Ventures) Tr. 163).
919. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 41-42) (*in camera*)).
920. MCED tests require the ability to detect one molecule of DNA in ten milliliters of blood. (Lengauer (Third Rock Ventures) Tr. 163).
921. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 23) (*in camera*)).
922. [REDACTED]

[REDACTED] }  
(PX7045 (Chudova (Guardant) IHT at 53) (*in camera*)).

923. [REDACTED]

[REDACTED] }

(PX7045 (Chudova (Guardant) IHT at 30-31) (*in camera*)).

924. Dr. Vogelstein testified that Illumina’s NGS sequencers allow his lab to “evaluate the majority of DNA template molecules in a small amount of plasma,” which is “critical because there are only a small, very small, number of molecules in plasma that come from [a] tumor” including as “little as 1 in 10,000 molecules or 1 in 100,000 molecules.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 58)).

**C. MCED TESTS REQUIRE HIGH-THROUGHPUT, HIGHLY ACCURATE, LOW-COST NGS PLATFORMS**

925. [REDACTED] (PX7121 (Otte (Freenome) Dep. at 48-50) (*in camera*)).

926. Deep sequencing drives the performance of cancer screening tests because it “[i]mproves signal-to-noise, making small amounts of ctDNA detectable” and it “[c]over[s] more genes and mutations” which drive sensitivity and specificity. (PX2005 (Illumina) at 006-007 (ScreenCo – Early Cancer Detection on a Global Scale)).

927. [REDACTED] } (Chudova (Guardant) Tr. 1208-09) (*in camera*).

928. Natera’s Fesko testified that [REDACTED] } (PX7111 (Fesko (Natera) Dep. at 50-52) (*in camera*)).

929. [REDACTED]

[REDACTED] } (Conroy (Exact Sciences) Tr. 1580; 1582 (*in camera*)).

930. Illumina’s Mr. Naclerio testified that “Illumina has really competed on primarily three parameters since the beginning, cost, throughput, and quality or accuracy. And [ ] at this time, we believed we were still the leaders in all three of those parameters.” (PX7060 (Naclerio (Illumina) IHT at 76)).

**1. MCED Tests Need High-Throughput NGS Machines to Sample an Extremely High Number of cfDNA Fragments from Each Blood Sample**

931. [REDACTED] (deSouza (Illumina) Tr. 2265 (*in camera*)).

932. [REDACTED] (Conroy (Exact Sciences) Tr. 1580-81).

933. “Reads per run” is a measurement of throughput and means the number of DNA library molecules an instrument can sequence on each run of the instrument. (PX0114 at 002, Illumina Sequencing Platforms, <https://www.illumina.com/systems/sequencing-platforms.html> (last visited Apr. 6, 2022)); see PX0035 at 002 (An Introduction to Next-Generation Sequencing Technology, <https://www.illumina.com/Documents/products/Illumina Sequencing Introduction.pdf> (last visited Apr. 6, 2022)); PX7044 (Stahl (Invitae) IHT at 87 (“Q. When you say ‘throughput,’ is that another way of talking about the depth of read that we were just talking about or is that a different attribute of the machine? A. It is that attribute, so how many millions of reads are you getting.”); PX7070 (Felton (Thermo Fisher) IHT at 30-31 (“Q Can you explain the unit of measurement that you used to describe throughput, the reads per run? A. Sure. So read, as I’ve described earlier in the deposition, is a single contiguous length of DNA sequence from, in our case, a chip. So each well on a chip can generate a read, and we typically generate those reads in the range of 200 to 400 base pairs per sequence. So we’re generating 60 to 80 million 200 to 400 base-pair sequencers per run.”)).

934. Multiplying the number of reads per run by the length of each read calculates the instrument’s output in terms of gigabases per run. (PX7044 (Stahl (Invitae) IHT at 80); PX7070 (Felton (Thermo Fisher) IHT at 31) (Gigabases is “how much overall sequence information is provided. The overall sequencing information and gigabases is a combination of the number of reads times the length of the read.”)).

935. [REDACTED] } (Chudova (Guardant) Tr. 1222-23) (*in camera*)).

936. In defining the term throughput in the context of cancer screening, Natera’s Dr. Rabinowitz testified:

[REDACTED]

(PX7054 (Rabinowitz (Natera) IHT at 47) (*in camera*)).

937.

[REDACTED] (Chudova (Guardant) Tr. 1210) (*in camera*)).

938.

[REDACTED] } (Chudova (Guardant) Tr. 1211) (*in camera*)).

939.

[REDACTED] } (deSouza (Illumina), Tr. 2265-66 (*in camera*)).

940.

[REDACTED] (PX7100 (Chudova (Guardant) Dep. at 60-61) (*in camera*)).

941.

[REDACTED] (PX7100 (Chudova (Guardant) Dep. at 60-61) (*in camera*)).

942.

[REDACTED]

[REDACTED]

(PX7100 (Chudova (Guardant) Dep. at 61-62) (*in camera*)).

943. [REDACTED]  
[REDACTED] (PX7045 (Chudova (Guardant) IHT at 50) (*in camera*)).
944. [REDACTED]  
[REDACTED] } (Chudova (Guardant) Tr. 1207-08 (*in camera*)).
945. Freenome CEO, Michael Nolan testified at trial that the high throughput of Illumina’s sequencer also enables Freenome to “keep []costs in a position with proper ratios.” (Nolan (Freenome) Tr. 2716).
946. Freenome CEO, Michael Nolan testified at trial that the high throughput of Illumina’s NGS sequencer will enable “performing billions of tests a year.” (Nolan (Freenome) Tr. 2715).
947. Mr. Nolan further testified that the high throughput of Illumina’s sequencer also enables Freenome to achieve “operational efficiency.” (Nolan (Freenome) Tr. 2716).
948. Freenome’s Nolan also explained at trial that “there’s probably no higher priority” than the ability of an NGS sequencer to scale, because, “even with a relatively small share of [the] market,” Freenome will be performing “millions of tests a year.” (Nolan (Freenome) Tr. 2720).
949. In discussing potential alternatives to Illumina’s NGS sequencers for Freenome’s cancer screening test, Mr. Nolan testified, [REDACTED]  
[REDACTED] } (PX7094 (Nolan (Freenome) Dep. at 221-223) (*in camera*)).
950. Freenome’s Otte testified that, for example, [REDACTED]  
[REDACTED] } (PX7055 (Otte (Freenome) IHT at 17-19) (*in camera*)).
951. [REDACTED]  
[REDACTED] } (PX7111 (Fesko (Natera) Dep. at 52) (*in camera*)).
952. According to Thermo Fisher’s Dr. Felton, MCED tests require a “high throughput platform such that you could screen through many thousands of patient samples per day or per week or tens of thousands per week because population screening for early cancer is likely to be a very sample-intensive solution.” (PX7070 (Felton (Thermo Fisher) IHT at 52)).
953. Dr. Felton testified that multi-cancer early detection is an application suited for high-throughput NGS sequencers because “[t]he collection of samples from a wide area of the population is inherently easier if it’s funneled into a central facility . . . and then running



those samples on a high throughput platform would reduce the amount of labor time involved in the processing of said samples.” (Felton (Thermo Fisher) Tr. 2002).

954. Dr. Felton testified that a sequencing platform would have to be able to produce “a large number of reads” per run to be used for MCED tests because “we would expect there to be a high number of samples, and, therefore, a system with a high throughput capability would be much preferable to one with a small output that you would have to run multiple times.” (Felton (Thermo Fisher) Tr. 1990-1991).

**2. MCED Tests Need NGS with High Accuracy and Low Error Rates to Correctly Identify ctDNA and Increase Sensitivity and Specificity**

955. [REDACTED] } (Conroy (Exact) Tr. 1581).

956. [REDACTED] } (deSouza (Illumina) Tr. 2266 (*in camera*)).

957. Dr. Lengauer testified that for Thrive’s CancerSEEK test, [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 66-67 (*in camera*))).

958. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 70 (*in camera*))).

959. [REDACTED] } (PX7068 (Perettie (FMI-Roche) IHT at 69) (*in camera*)).

960. [REDACTED] } (Chudova (Guardant) Tr. 1208) (*in camera*)).

961. Guardant’s Dr. Chudova explained how accuracy affects sequencing costs, “to correct the error rate inherent in the sequencing technology, we oversequence, which means we read each molecule more than once to try to minimize the error.” ((PX7045 (Chudova (Guardant) IHT at 28-31)).

962. Dr. Chudova explained that an NGS platform’s accuracy influences sequencing costs because: “you can trade off throughput for error, so that means if you all of a sudden want to tolerate, instead of .3 percent, let’s say .5 percent error rate, you need to sequence that molecule more times and you need to have higher throughput.” (PX7045 (Chudova (Guardant) IHT at 31-34).

963. Dr. Rabinowitz testified that a “sequencer has to be very accurate in saying what series of nucleotides constitute each fragment, and the sequencer needs to be stable. In other words,

[Natera] need[s] to model the noise of the sequencer very precisely so that [Natera] can calibrate out that noise[.]” (Rabinowitz (Natera) Tr. 310).

964. “If the sequencer is accurate sometimes, not accurate [other times], and has a variable noise model or run-to-run instability, that creates major issues.” (Rabinowitz (Natera) Tr. 310).

965. [REDACTED]  
 (Rabinowitz (Natera) Tr. 362 (*in camera*)).

966. Low NGS platform accuracy increases costs to run a cancer screening test because low accuracy requires more “sequencing . . . to tell mutation from error.” (PX7042 (Gao (Singlera) IHT at 46)).

967. Dr. Gao elaborated that if the accuracy is low you need to resequence, but “[w]ith Illumina you need less sequencing” or “coverage” so “if you look at the . . . raw sequencing reagent cost, [a less accurate NGS sequencer] may be a little bit cheaper. However if you look at the required amount of sequencing needed to tell mutation from error, you end up paying more[.]” (PX7042 (Gao (Singlera) IHT at 46-47)).

968. Freenome CEO, Michael Nolan, testified at trial that the accuracy of an NGS sequencer “an important parameter overall for [an MCED] test, and it’s of course important for [Freenome] in [its] research and product development to have accuracy.” (Nolan (Freenome) Tr. 2720).

969. [REDACTED] (PX4140 (Grail) at 007, 010 (“R&D Portfolio Planning – Part B: Sequencing Technology,” last modified Apr. 14, 2019) (*in camera*)).

970. Illumina’s Mr. Aravanis testified “the one area [] where Illumina is superior in a meaningful way is around data accuracy, so the accuracy of the Oxford Nanopore reads is not as good as the Illumina reads.” (PX7065 (Aravanis (Illumina) IHT at 158)).

971. Dr. Vogelstein testified that the accuracy of Illumina’s NGS sequencers “approaches about one error in several thousand bases” which he explained is “absolutely essential to get the specificity that you need for an earlier detection test” because “[o]therwise, you’ll get too many false positives.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 58-59)).

972. To deliver sufficiently accurate results, MCED test developers must use sequencing technology with low error rates. ((PX7075 (Stahl (Invitae) Dep. at 71-74) (describing how some NGS platforms’ error rates are prohibitively high for Invitae’s applications)).

973. In an internal presentation to Illumina’s Science & Technology Committee, Illumina executives recognized that [REDACTED]  
 [REDACTED] (PX2013 (Illumina) at 003 (Cancer Screening, Apr. 28, 2020) (*in camera*)).

974. An internal presentation made to Illumina’s Science & Technology Committee recognizes that { [REDACTED] } (PX2013 (Illumina) at 003 (Cancer Screening, Apr. 28, 2020) (*in camera*)).

975. Illumina’s CEO Mr. deSouza testified that Illumina’s expertise is “try[ing] [to] continue to move the accuracy of the reads of our sequencers using machine learning.” (PX7072 (deSouza (Illumina) IHT at 187)).

**3. MCED Tests Need Low-Cost Sequencing to Screen the General Population**

976. Because MCED test developers ultimately seek to regularly test most of the adult population in the United States, low costs are important to the success of an MCED test. (*See supra* Sections II.C.6. (MCED Tests Seek to Detect Multiple Cancers Simultaneously in Asymptomatic Individuals) and III.C.1. (MCED Tests Will Have Distinct Pricing and Reimbursement from Other Oncology Tests)).

977. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 127-28) (*in camera*)).

978. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 68-69) (*in camera*); PX7102 (Gao (Singlera) Dep. at 27); PX7045 (Chudova (Guardant) IHT at 43-44) (*in camera*); Nolan (Freenome) Tr. 2723; Ofman (Grail) Tr. 3302.

979. Thrive’s Lengauer testified that [REDACTED]

[REDACTED]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 68-69) (*in camera*)).

980. Freenome’s Otte testified that, for example, [REDACTED] } (PX7055 (Otte (Freenome) IHT at 17-19) (*in camera*)).

981. Dr. Gao explained that Singlera chooses to run its cancer screening test on Illumina’s NGS platform in part because “it’s very cost economic” in terms of the number of reads per run. (PX7102 (Gao (Singlera) Dep. at 27)).
982. Singlera’s Gao explained that a cancer “screen[ing] test has to be very cheap,” “unlike [a] confirmation test” in order to be commercially viable. (PX7042 (Gao (Singlera) IHT at 50-51)).
983. [REDACTED] (PX7045 (Chudova (Guardant) IHT at 43-44) (*in camera*)).
984. Mr. Nolan indicated at trial that keeping the cost of NGS sequencing and the related consumables low is important to Freenome because they are the “majority of [the] cost of goods today in [Freenome’s] different prototypes.” (Nolan (Freenome), Tr. 2723).
985. Dr. Chahine testified at trial that the R&D process to develop a screening test is “extremely expensive,” and the two major costs are “acquiring the actual samples” to conduct the analysis and the sequencing the samples. (Chahine (Helio) Tr. 1035-36).
986. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 30 (*in camera*)).
987. Dr. Rabinowitz testified that “uniformity” of coverage across regions of the genome being screened is a key factor for the cost of sequencing—for Natera “all the regions of DNA that [Natera] want[s] to look at should have a similar amount of sequencing.” (Rabinowitz (Natera) Tr. 310-11).
988. Dr. Rabinowitz explained the significance of a sequencer’s lack of uniformity:
- If you have lack of uniformity in the sequencer, you’ll get a lot of information about one region of the chromosome and much less information about another region, and the result of that is you have to do a whole lot more sequencing, because you want to get a minimum amount of coverage and the coverage is largely the richness of the data that you can get about what’s going on at that particular region of the chromosome.
- (Rabinowitz (Natera) Tr. 311).
989. Dr. Rabinowitz further testified that “especially for the oncology tests, you want to do as much sequencing as your costs will allow, because the more sequencing you do, the broader the things that you can look at, the better you are at capturing single molecules, and the better the sensitivity and specificity of your test.” (Rabinowitz (Natera) Tr. 311).
990. Dr. Rabinowitz explained that the sequencing data generated connects directly with test performance: “[T]he more sequencing that one can do, the better performance of the test,

especially in the oncology context, where you want to go down to sort of single-molecule detection levels.” (Rabinowitz (Natera) Tr. 311-12).

991. [REDACTED] (PX8354 (Roche) at 004 (Monitoring and Screening Markets, Jan. 29, 2021) (*in camera*)).
992. Customers requiring the sequencing of a large number of samples require sequencers with a low price per sample. (Felton (Thermo Fisher) Tr. 2000-01).
993. Thermo Fisher’s Felton acknowledged that NGS instruments with a “low cost per sample [are] likely to be the major requirement” for MCED tests. (PX7070 (Felton (Thermo Fisher) IHT at 52)).
994. Dr. Vogelstein testified that “the sequencing component of the test is the most expensive part of” the research performed at his lab. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 69)).
995. Dr. Vogelstein testified that his “lab’s goal is to ultimately create tests that are affordable for all” and “[t]herefore, the cost and the throughput of the sequencing are key.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 68)).
996. Dr. Vogelstein testified that “[r]esearchers in the field are acutely aware of Illumina’s sequencing because sequencing is a major cost in the analysis of CF DNA” and “[t]he cost of sequencing is therefore a major factor that drives the cost of creating a test for the public that could become part of the battery of relatively routine tests associated with an annual physical.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 67-68)).
997. [REDACTED] (PX8399 (Henry (PacBio) Decl. ¶ 5) (*in camera*)).
998. Grail’s Aaron Freidin explained, [REDACTED] (PX7066 (Freidin (Grail) IHT at 216-17) (*in camera*)).
999. Grail witnesses also testified at trial that NGS sequencing needs to be low cost, including Grail’s CEO Hans Bishop who testified that it is “a very high priority [in] reducing the cost of our test.” (Bishop (Grail), Tr. 1368).
1000. [REDACTED] (Bishop (Grail) Tr. 1446 (*in camera*)).

1001. Grail’s Dr. Ofman testified that “we need to get the cost of the [MCED] test down” “to achieve [Grail’s] mission of providing access to this type of technology to adults worldwide to . . . dramatically improve the cancer detection rate.” (Ofman (Grail) Tr. 3302).
1002. Grail’s ordinary course documents state, “Illumina represents >50% of GRAIL V2 Product Cost of goods sold.” (PX4079 (Grail) at 004 (ILMN/Grail, Jan. 16, 2020) (listing total Illumina COGS at 56% and non-royalty COGS at 50%); *see* (PX4040 (Grail) at 005 (Email from K. Martin, Grail, to A. Freidin, Grail, Feb. 12, 2020) (listing a range of Illumina COGS from 32% to 54% depending on sales volumes and Galleri version number)).

**4. An MCED Developer Planning to Sell a Kitted MCED Test Requires an FDA-Cleared NGS Platform**

1003. A distributed kit (or “kitted”) in-vitro diagnostic test is where the test developer generates a version of the test that can then be distributed to third-party CLIA/CAP-certified labs to be processed. (Goswami (Illumina) Tr. 3185-87).
1004. A kitted IVD is an IVD test that has received pre-market approval from the FDA permitting analysis by independent testing providers. (Goswami (Illumina) Tr. 3186-87).
1005. The distributed kit IVD test developer has “responsibility for quality control and quality analysis” of the distributed kit IVD test. (Goswami (Illumina) Tr. 3187).
1006. An NGS-based kitted IVD test uses dedicated “DX” versions of Illumina’s NGS platforms, which have obtained 510(k) clearance from the FDA. (Goswami (Illumina) Tr. 3188-89; *see* PX6056 (Illumina) at 051 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*) ( [REDACTED] )).
1007. It is Illumina’s responsibility to get FDA clearance for “the box that runs the test, and supply the core consumables that go along with the box” for a test developer developing a test on an Illumina’s Dx platform. (Goswami (Illumina) Tr. 3188-89).
1008. Illumina then provides a device master file to the FDA when a kitted IVD test developer is seeking FDA approval for its test. (Goswami (Illumina) Tr. 3224).
1009. A distributed kit IVD test developer must follow FDA guidelines and submit to regular FDA audits following PMA approval of a distributed kit IVD. (Goswami (Illumina) Tr. 3187).
1010. An executive from Invitae, an Illumina oncology customer though not an MCED test developer, testified that, in order to offer a cancer screening test as “a distributed IVD, the FDA mandates that the next-generation sequencer be cleared, so it has to have a 510(k) clearance. That clearance then must be part of the companion diagnostic device.” (PX7044 (Stahl (Invitae) IHT at 51-52)).
1011. Singlera’s Dr. Gao testified that Singlera plans to commercially launch its screening test as an “IVD kit[ted test.]” (PX7102 (Gao (Singlera) Dep. at 45-46)).

1012. When asked why Singlera chose to use Illumina’s NGS platform for its cancer screening test, Dr. Gao testified, “the first reason is the NextSeqDx is FDA 510K cleared.” (PX7102 (Gao (Singlera) Dep. at 27)).
1013. Dr. Gao explained that Singlera “had to use a sure [sic] FDA cleared device, so we choose [Illumina’s] NextSeqDx, even though NovaSeq/HiSeq will also do the job, even cheaper. But because they are not FDA cleared, we do not want to run the risk.” (PX7102 (Gao (Singlera) Dep. at 27)).
1014. In discussing the prospect of Singlera running its cancer screening test on a sequencing platform that has not secured FDA clearance, Dr. Gao indicated, “[i]t’s the -- we call it’s the no deal kind of a situation. If you don’t have FDA clearance, we cannot go with you.” (PX7042 (Gao (Singlera) IHT at 53)).
1015. [REDACTED]
1016. [REDACTED]
1017. [REDACTED]
1018. Invitae’s Stahl explained why Illumina’s NGS platform is the only option for an oncology customer, like Invitae, or any MCED test developer, to sell a cancer screening test as a distributed IVD kit:

It comes down to FDA regulation. So for a distributed IVD, the FDA mandates that the next-generation sequencer be cleared, so it has to have a 510(k) clearance. That clearance then must be part of the companion diagnostic device. . . . So unless you have an agreement with Illumina to agree when the FDA request it to send them their sequencing package, you have no way to get approval. Therefore, without them, it -- I mean, right now, it’s actually -- it’s impossible. You can’t do it.

(PX7044 (Stahl (Invitae) IHT 51-52)).

**D. ONLY ILLUMINA NGS PLATFORMS MEET THE REQUIREMENTS OF MCED TESTS**

1019. As shown below, every MCED test developer testified that they need and rely on Illumina NGS as the sole NGS provider that meets their tests’ needs. (*See* Section V.D.2).
1020. According to Illumina, more than 90% of the world’s sequencing data is generated using Illumina NGS technology: “Leaders turn to Illumina technology for the high-quality sequencing data our instruments produce. They’ve done so for decades. With more than 90% of the world’s sequencing data generated by Illumina sequencing by synthesis (SBS)

chemistry, and > 17,000 active Illumina sequencers deployed globally, our solutions enable our customers to make discoveries that were unimaginable even a few years ago.” (PX0121, Illumina, Choosing an NGS Company, <https://www.illumina.com/science/technology/next-generation-sequencing/choose-ngs-company.html> (last visited Apr. 6, 2022)).

**1. Illumina’s Industry Leading NGS Technology**

a) Instruments

1021. Illumina’s identifies three categories of “production-scale sequencers”: the “NextSeq 550 Series,” the “NextSeq 1000 & 2000,” and the “NovaSeq 6000.” (PX0114, Illumina, Sequencing Platforms, <https://www.illumina.com/systems/sequencing-platforms.html> (last visited Apr. 6, 2022)).

1022. [REDACTED] } (PX2032 (Illumina) at 014 (Illumina, AMR 2021 Revenue Forecast, Oct. 9, 2020) (*in camera*)).

(1) NovaSeq

1023. The NovaSeq is Illumina’s “high-throughput platform.” (Goswami (Illumina) Tr. 3191-92).

1024. The NovaSeq is the only sequencer for which Illumina identifies “cell-free sequencing & liquid biopsy analysis” and “methylation sequencing” as “key applications.” (PX0114, Sequencing Platforms, <https://www.illumina.com/systems/sequencing-platforms.html> (last visited Apr. 6, 2022)).

1025. A “flow cell” is a surface onto which a prepared library of DNA molecules is attached for the purpose of sequencing. (PX7104 Aravanis (Illumina) Dep. at 117)).

1026. “Reads” are the strings of nucleotide bases in each library molecule being sequenced. (PX0035 at 002, Illumina, An Introduction to Next-Generation Sequencing Technology, <https://www.illumina.com/Documents/products/Illumina Sequencing Introduction.pdf> (last visited Apr. 6, 2022)).

1027. [REDACTED]  
[REDACTED] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 15-16 (RFA No. 17) (*in camera*)).

1028. [REDACTED]  
[REDACTED] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 16 (RFA No. 18) (*in camera*)).



(2) NextSeq Series

- 1029. The NextSeq is Illumina’s “medium or mid-throughput platform.” (Goswami (Illumina) Tr. 3191).
- 1030. Illumina identifies the NextSeq as a “production-scale sequencer.” (PX0114, Sequencing Platforms, <https://www.illumina.com/systems/sequencing-platforms.html> (last visited Apr. 6, 2022)).
- 1031. Illumina identifies the NextSeq as capable of “cell-free sequencing & liquid biopsy analysis” and “methylation sequencing.” (PX0114, Illumina, Sequencing Platforms, <https://www.illumina.com/systems/sequencing-platforms.html> (last visited Apr. 6, 2022)).
- 1032. “Cell-free sequencing & liquid biopsy analysis” and “methylation sequencing” are not identified as “key applications” for NextSeq sequencers. (PX0114, Illumina, Sequencing Platforms, <https://www.illumina.com/systems/sequencing-platforms.html> (last visited Apr. 6, 2022)).

(3) Illumina’s Other Platforms

- 1033. Illumina offers a number of other benchtop sequencers that are not designated as “production-scale sequencers,” including the iSeq 100, the MiniSeq, and the MiSeq series. (PX0114, Illumina, Sequencing Platforms, <https://www.illumina.com/systems/sequencing-platforms.html> (last visited Apr. 6, 2022)).
- 1034. Illumina’s MiSeq is a “low-throughput platform.” (Goswami (Illumina) Tr. 3191). That means it “can run tests that have a low number of reads per test, so something like NIPT or an infectious disease test or a small oncology panel.” (Goswami (Illumina) Tr. 3192).
- 1035. Generally, a low-throughput instrument will be used for an application with low reads or if the lab does not process many samples (i.e., ten to twenty samples at a time). (Goswami (Illumina) Tr. 3193).

(4) Illumina’s Proactive Performance Monitoring System

- 1036. [REDACTED] } (PX7076 (Berry (Illumina) Dep. at 27-30, 35-36); PX6056 (Illumina) at 047 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
- 1037. Proactive provides customers with access to improved service. (PX7076 (Berry (Illumina) Dep. at 36-37)).
- 1038. [REDACTED] (PX6056 (Illumina) at 047 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

1039. Proactive provides Illumina with “the ability to monitor instrument use, specifically as it relates to run metrics” and grants Illumina access to information on the number of runs a customer performs on each instrument, as well as the type of flow cell in use on each instrument. (PX7076 (Berry (Illumina) Dep. at 27-30, 39-40)).

(5) [REDACTED]

(a) *Technical Improvements/Updates – Process to Market*

1040. Illumina continuously makes improvements and updates to the performance and feature set of its existing platforms:

JUDGE CHAPPELL: Do you know if there are frequent – I’m not sure of the terminology – but software updates or something that would need to be added to make the machine perform properly?

THE WITNESS [Nicole Berry, Illumina SVP and General Manager of the Americas Commercial Region]: Sure. So we are continuously seeking to improve performance and, you know, the feature set of our instruments and user friendliness as it relates to things like software. So, yes, software updates are something that we would typically provide and make part of our continuous sort of update and improvement process.

Those oftentimes could be actually administered remotely. If the customer opted into sort of, you know, a remote connectivity, we could potentially just push an update to the customer’s instrument without having to actually go into the lab and, you know, sit at it and put disks in a hard drive, you know, the old-fashioned way.

(Berry (Illumina) Tr. 675-76).

1041. Illumina’s Ms. Berry testified about Illumina’s “track record in terms of our technology innovation and new product introduction process,” stating that Illumina has introduced new instrument platforms and new chemistries within instrument platforms “on a very regular basis.” (Berry (Illumina) Tr. 714-15).

(b) [REDACTED]

1042. [REDACTED] } (deSouza (Illumina) Tr. 2278 (*in camera*)).

1043. [REDACTED] (deSouza (Illumina) Tr. 2278 (*in camera*)).

(c) [REDACTED]

1044. [REDACTED] (Aravanis (Illumina) Tr. 1794 (*in camera*); deSouza (Illumina) Tr. 2271 (*in camera*); PX2169 (Illumina) at 022, 025 (Illumina Strategic Plan 2021-2025, Oct. 23, 2020) (*in camera*); PX5026 (Illumina) at 009 (FY20-25 Strategic Plan Initial Revenue Discussion, Jun. 4, 2020 (*in camera*))).

1045. [REDACTED] (RX1254 (Illumina) at 009 [REDACTED] (*in camera*)).

1046. [REDACTED] (Aravanis (Illumina) Tr. 1797; PX6056 (Illumina) at 017 (Illumina, Narrative Response to the Second Request, Mar. 1, 2021) (*in camera*)) ([REDACTED] [REDACTED]); RX1254 (Illumina) at 010 [REDACTED] (*in camera*)); PX2169 (Illumina) at 025 (Illumina Strategic Plan 2021-2025, Oct. 23, 2020) ([REDACTED] [REDACTED]); [REDACTED]

b) Illumina Consumables

1047. Illumina sells multiple versions of flow cells (SP, S1, S2, and S4): “the main difference between these flow cells is that they have different outputs,” with the S4 providing the highest output of data in a single run of the sequencer. (PX7104 (Aravanis (Illumina) Dep. at 117-122)).

1048. The S4 flow cell for the NovaSeq can load 10 billion DNA library fragments, yielding 10 billion single-end reads (or 20 billion paired-end reads if each fragment is read both forward and backward). (PX0085 at 001, Illumina, NovaSeq 6000 System Specifications, <https://www.illumina.com/systems/sequencing-platforms/novaseq/specifications.html> (last visited Apr. 6, 2022)).

1049. The NovaSeq is capable of processing two flow cells simultaneously, and thus is capable of reading 20 billion library fragments, yielding 20 billion single-end reads (or 40 billion paired end reads), in a single 44-hour run of the instrument. (PX0085 at 001-002, Illumina, NovaSeq 6000 System Specifications, <https://www.illumina.com/systems/sequencing-platforms/novaseq/specifications.html> (last visited Apr. 6, 2022)).

1050. Many of Illumina’s consumables are off-the-shelf products for use in a variety of sequencing applications. (Berry (Illumina) Tr. 827).

1051. Ms. Berry admitted at trial that Illumina also sells custom library prep kits to its NGS sequencing customers. (Berry (Illumina) Tr. at 928; PX7063 (Berry (Illumina) IHT at 33).

1052. In 2020, Illumina’s consumable sales accounted for 71 percent of Illumina’s total revenue. (PX0061 at 007 (Illumina 2020 Form 10-K)).

**2. MCED Test Developers Testified That They Need and Rely on Illumina NGS as Their Only NGS Option**

1053. Illumina sells NGS equipment to Grail, Exact, Natera, Guardant, Freenome, Singlera, and Foundation Medicine. (See Berry (Illumina) Tr. 650-51).

a) Grail

1054. Grail’s Galleri test relies on Illumina’s NGS instruments and reagents. (PX0043 at 011 (Grail 2020 Form S-1); PX7069 (Bishop (Grail) IHT at 208-10)).

1055. [REDACTED] } (Jamshidi (Grail) Tr. 4029 (*in camera*); (Bishop (Grail) Tr. 1336-37; 1381)).

1056. [REDACTED] } (Jamshidi (Grail) Tr. 4029 (*in camera*)).

1057. [REDACTED] (Jamshidi (Grail) Tr. 4029 (*in camera*)).

1058. [REDACTED] (PX4212 (Grail) at 018 [REDACTED] (*in camera*)).

1059. [REDACTED] (PX4140 (Grail) at 007, 010 ( R&D Portfolio Planning – Part B: Sequencing Technology) (*in camera*)).

1060. [REDACTED] } (Freidin (Grail) Tr. 3066 (*in camera*)).

1061. [REDACTED] (PX7066 (Freidin (Grail) IHT at 133) (*in camera*)).

1062. [REDACTED]

- [REDACTED] (PX7066 (Freidin (Grail) IHT at 126) (*in camera*)).
1063. [REDACTED] (PX6049 (Grail) at 023 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).
1064. [REDACTED] } (PX4140 (Grail) at 003 (R&D Portfolio Planning – Part B: Sequencing Technology) (*in camera*)).
1065. [REDACTED] (PX4140 (Grail) at 003, 009-010 (R&D Portfolio Planning – Part B: Sequencing Technology) (*in camera*)).
1066. Grail has never physically performed technical evaluations of non-Illumina sequencers. (PX7103 (Jamshidi (Grail) Dep. at 33)).
1067. In Grail’s Form S-1 filed with the Securities and Exchange Commission, Grail detailed in the “Risk Factors” section, “[w]e rely on Illumina, Inc. as a sole supplier for our next-generation sequencers and associated reagents. . . .” (PX0043 at 011 (Grail 2020 Form S-1)).
1068. In an internal email, Grail’s Board Chair, Cathy Friedman, referred to “Illumina’s position as a ‘necessary tax’ on the entire genomics industry . . . .” (PX4375 (Grail) at 001 (Email from G. Golumbeski, Grail, to C. Friedman, Grail, Oct. 10, 2018) (referring to a quote from Guardant’s S-1, which states, “We rely on Illumina as the sole supplier of the sequencers, and as the sole provider of maintenance and repair services for these sequencers.”)).
1069. [REDACTED] } (PX7066 (Freidin (Grail) IHT at 212-13; PX6049 (Grail) at 023 (Grail, Narrative Response to Second Request, Mar. 1, 2021)) (*in camera*)).
1070. [REDACTED] } (Freidin (Grail) Tr. 3065 (*in camera*)); *see* (Bishop (Grail) Tr. 1381) (explaining that Grail’s earlier research was conducted on Illumina’s NGS)).
1071. [REDACTED] (Freidin (Grail) Tr. 3066 (*in camera*)).
1072. Grail’s former CEO Mr. Bishop testified at trial that Grail has stayed with Illumina NGS because it is the “technology we know and that works.” (Bishop (Grail) Tr. 1381).

1073. Galleri has been validated for use on only an Illumina NGS sequencer. (Bishop (Grail) Tr. 1337).
1074. Grail does not have a validated alternative to Illumina’s NGS platforms for Galleri. (Bishop (Grail) Tr. 1337-38).
1075. Grail’s former CEO, Hans Bishop, testified that Illumina is Grail’s “only [supplier of NGS instruments and reagents] that we validated with our technology, so if they’re not available to us, we don’t have a validated alternative.” (PX7069 (Bishop (Grail) IHT at 210)).
1076. Mr. Bishop explained that Illumina’s status as Grail’s only validated sequencer, “means that all the analytical validation and regulatory compliance documents that we’ve done that you’re required to do to show our tests work is done, again, with all the different suppliers on that list, and if we had to substitute one, we would have to do that work again.” (PX7069 (Bishop (Grail) IHT at 210)).
1077. [REDACTED] } (PX4085 (Grail) at 011 (Grail, “Critical Materials Landscape, Dec. 5, 2018) (*in camera*)).
1078. [REDACTED] (PX6049 (Grail) at 023 (Grail, Narrative Response to Second Request) (*in camera*)).
1079. [REDACTED] } (Freidin (Grail) Tr. 3065-66 (*in camera*); PX7066 (Freidin (Grail) IHT at 133) (*in camera*)).
1080. [REDACTED] } (PX6049 (Grail) at 023 (Grail, Narrative Response to Second Request) (*in camera*)).
1081. [REDACTED] } (PX6082 (Grail) at 009 (Grail Response to Request for Admission) (*in camera*)).
1082. [REDACTED] (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).
1083. Grail’s Form S-1—a filing submitted to the Securities and Exchange Commission—warns that a qualitative substitute for Illumina “may not be available at all”:

In the case of attempting to obtain an alternative supplier for Illumina, Streck, or Twist, replacement instruments and associated reagents, tubes, and panels that meet our quality control and performance requirements may not be

available at all, or may not be available on reasonable terms or in a timely manner.

(PX4082 (Grail) at 034 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

b) [REDACTED]

1084. [REDACTED]

1085. [REDACTED]

1086. [REDACTED]

1087. [REDACTED]

1088. [REDACTED]

1089. [REDACTED]

1090. [REDACTED]

1091. [REDACTED]

1092. [REDACTED]

1093. [REDACTED]

1094. [REDACTED]

1095. [REDACTED]

c) [REDACTED]

1096. [REDACTED]

1097. [REDACTED]

1098. [REDACTED]

1099. [REDACTED]

1100. [REDACTED]

1101. [REDACTED] } (PX7111 (Fesko (Natera) Dep. at 47) (*in camera*)).

1102. [REDACTED]

1103. [REDACTED]



[REDACTED]

1104. [REDACTED]

1105. [REDACTED]

[REDACTED]

[REDACTED]

d) Guardant

1106. [REDACTED] } (Chudova (Guardant) Tr. 1196) (*in camera*)).

1107. [REDACTED] (Chudova (Guardant) Tr. 1300 (*in camera*)).

1108. [REDACTED] (Chudova (Guardant) Tr. 1212 (*in camera*); see also PX7045 (Chudova (Guardant) IHT at 22-23; 39-40) (*in camera*)).

1109. [REDACTED] (Chudova (Guardant) Tr. 1207 (*in camera*)).

1110. [REDACTED] (Chudova (Guardant) Tr. 1208 (*in camera*)); PX7045 (Chudova (Guardant) IHT at 40-41) (*in camera*)).

1111. [REDACTED] (Chudova (Guardant) Tr. 1212 (*in camera*)).

1112. [REDACTED] } (Chudova  
(Guardant) Tr. at 1212-13 (*in camera*)).

1113. [REDACTED] } (Chudova  
(Guardant) Tr. 1212-13 (*in camera*)).

1114. [REDACTED] }  
(Chudova (Guardant) Tr. 1213 (*in camera*)).

1115. [REDACTED]  
[REDACTED] (Chudova (Guardant) Tr. 1213 (*in camera*)).

1116. [REDACTED]  
[REDACTED] } (Chudova (Guardant) Tr. 1224 (*in camera*)).

1117. [REDACTED]  
[REDACTED] (Chudova (Guardant) Tr. 1224 (*in camera*)).

1118. [REDACTED]  
[REDACTED] (Chudova (Guardant) Tr. 1214 (*in camera*)).

1119. [REDACTED]  
[REDACTED]  
(Chudova (Guardant) Tr. 1214 (*in camera*)).

1120. [REDACTED] } (Chudova (Guardant) Tr. 1215 (*in camera*)).

1121. [REDACTED] (Chudova (Guardant) Tr. 1215 (*in camera*)).

1122. [REDACTED] (Chudova (Guardant) Tr. 1215 (*in camera*)).

1123. [REDACTED] (Chudova (Guardant)  
Tr. 1215-16 (*in camera*)).

1124. [REDACTED] } (Chudova (Guardant) Tr. 1216 (*in camera*)).
1125. [REDACTED] (Chudova (Guardant) Tr. 1216 (*in camera*)).
1126. Guardant’s Chudova testified, “Illumina sequencers . . . are the only game in town. There are other sequencers on the market, but ultimately they don’t perform similarly. And [Guardant’s cancer screening] test has been optimized to work in an Illumina environment.” (PX7105 (Chudova (Guardant) Dep. at 239-40)).
1127. Guardant’s Chudova explained that [REDACTED] } (PX7045 (Chudova (Guardant) IHT at 40-41) (*in camera*)).
1128. Dr. Chudova testified that Next Generation Sequencing is a requirement for Guardant’s multicancer early detection test because it “need[s] parallel digital readout of every fragment in a highly, highly multiplex format, which means you need to run and read millions of molecules at a time or hundreds of millions of molecules at a time, and that is kind of the definition of what next-generation sequencing allows you to do.” (Chudova (Guardant) Tr. 1177).
1129. Referring to Illumina, Guardant’s Getty explained, [REDACTED] (Getty (Guardant) Tr. 2546 (*in camera*)).
1130. “Guardant wouldn’t exist without access to Illumina’s products.” (Getty (Guardant) Tr. 2510).
1131. Guardant cannot operate its assays without Illumina, its sole supplier for NGS. (Getty (Guardant) Tr. 2510).
1132. Guardant has no opportunity to move away from Illumina as its NGS provider. (Getty (Guardant) Tr. 2510).
1133. Guardant could not switch to another NGS system. (Getty (Guardant) Tr. 2510).
1134. Guardant’s Mr. Getty testified that nothing is comparable to Illumina’s NGS platforms. (Getty (Guardant) Tr. 2510).
1135. For both PacBio and Oxford Nanopore the “throughput is substantially less than what [Guardant] would require even for the smallest Guardant360 test.” (PX7045 (Chudova (Guardant) IHT at 45; *see* PX7045 (Chudova (Guardant) IHT at 45) (*in camera*)) [REDACTED]

[REDACTED]

1136. “[T]here’s a symbiotic relationship between Guardant Health and our activity and Illumina’s activities in terms of making sure we’re maximizing the value of the products they have delivered to us.” (Getty (Guardant) Tr. 2509).

1137. Guardant’s SVP of Commercial, Cancer Screening Core, William Getty, testified, “[w]ithout [Illumina], Guardant doesn’t exist.” (PX7040 (Getty (Guardant) IHT at 190)).

1138. In Guardant’s 2020 Form 10-K filed with the Securities and Exchange Commission, Guardant explained,

We rely on Illumina as the sole supplier of . . . sequencers and as the sole provider of maintenance and repair services for these sequencers. Any disruption in operations of Illumina . . . or termination or suspension of our relationships with them could materially and adversely impact our supply chain and laboratory operations . . . and thus our ability to conduct our business and generate revenue.

(PX0153 at 047 (Guardant, 2020 Form 10-K, Feb. 25, 2021)).

1139. Guardant has “[v]ery little” leverage in negotiating with Illumina. (PX7105 (Getty (Guardant) Dep. at 66)).

e) Freenome

1140. Freenome CEO, Michael Nolan, testified that Illumina’s sequencing technology is “really foundational” and a “pillar” in Freenome’s product development efforts. (Nolan (Freenome) Tr. 2714).

1141. Freenome uses Illumina’s NovaSeq sequencer for its multiomics platform. (Nolan (Freenome) Tr. 2714-15).

1142. [REDACTED] } PX7050 (Nolan (Freenome) IHT at 89-90 (*in camera*)); PX7055 (Otte (Freenome) IHT at 94-95 (*in camera*)).

1143. [REDACTED] } (PX7094 (Nolan (Freenome) Dep. at 142-44) (*in camera*)).

1144. Mr. Nolan testified that Freenome uses NGS in its multiomics platform as opposed to other technologies because it “gives [Freenome] great stability to detect the cancer in its – in the early stages. It’s a really foundational or – or pillar in overall product development efforts. . . . [I]t is really I would say the anchor tenant.” (Nolan (Freenome) Tr. 2713-14).

1145. Mr. Nolan testified that “anchor tenant” means “really foundational... [Freenome] get[s] a majority of the signal from next-generation sequencing [which is then] complemented by some of the other omics to be able to get better performance than [Freenome] would without it.” (Nolan (Freenome) Tr. 2714).
1146. In other words, “anchor tenant” is like the Macy’s in a shopping mall; it’s the “headliner, the major part of the model is next-generation sequencing.” (Nolan (Freenome) Tr. 2714).
1147. Freenome purchases NGS consumables from Illumina. (Nolan (Freenome) Tr. 2718).
1148. Freenome purchases NGS sequencer servicing from Illumina. (Nolan (Freenome) Tr. 2718).
1149. Mr. Nolan further explained, { [REDACTED] }  
 { [REDACTED] }  
 (Nolan (Freenome) Tr. 2759-60 (*in camera*)).
1150. In discussing potential alternatives to Illumina’s NGS sequencers for Freenome’s cancer screening test, Mr. Nolan testified, { [REDACTED] }  
 { [REDACTED] } (PX7094 (Nolan (Freenome) Dep. at 221-223) (*in camera*)).
1151. { [REDACTED] } (PX7094 (Nolan (Freenome) Dep. at 142-44) (*in camera*); PX7050 (Nolan (Freenome) IHT at 113) (*in camera*) ({ [REDACTED] })).
1152. In discussing the requirements to run Freenome’s cancer screening test, Mr. Nolan indicated that Freenome { [REDACTED] }  
 { [REDACTED] } (PX7094 (Nolan (Freenome) Dep. at 221-223) (*in camera*)).
1153. { [REDACTED] } (PX8378 (Freenome) at 002 (Email from M. Nolan, Freenome, to A. Welland, Illumina, Feb. 26, 2021) (*in camera*)).
1154. Freenome’s Nolan listed reasons why alternatives to Illumina’s sequencers were not viable options to run Freenome’s cancer screening test: { [REDACTED] }  
 { [REDACTED] } (PX7094 (Nolan (Freenome) Dep. at 222-223) (*in camera*)).
1155. Freenome CEO, Michael Nolan, testified at trial that Freenome cannot switch away from Illumina’s NGS platform because Freenome “just [does not] have . . . a suitable substitute to meet [Freenome’s] highest-level requirements.” (Nolan (Freenome) Tr. 2729).

1156. In discussing the viability of using alternatives to Illumina’s NGS platform, Freenome’s Otte testified, [REDACTED] } (PX7055 (Otte (Freenome) IHT at 69) (*in camera*)).
1157. Freenome’s former CEO Gabe Otte testified that [REDACTED] } (PX7055 (Otte (Freenome) IHT at 64-66) (*in camera*)).
1158. [REDACTED] (PX7121 (Otte (Freenome) Dep. at 48-50) (*in camera*))
1159. [REDACTED] (PX7055 (Otte (Freenome) IHT at 17-18) (*in camera*)).
1160. Mr. Otte testified that [REDACTED] } (PX7055 (Otte (Freenome) IHT at 72) (*in camera*)).
1161. [REDACTED] } (PX7055 (Otte (Freenome) IHT at 73-74) (*in camera*)).
1162. [REDACTED] (Nolan (Freenome) Tr. 2756-57 (*in camera*)).
1163. Freenome CEO, Michael Nolan, testified at trial that [REDACTED] } (Nolan (Freenome) Tr. 2759 (*in camera*)).
1164. At trial, Mr. Nolan, explained that Freenome [REDACTED] } (Nolan (Freenome) Tr. 2759-60 (*in camera*)).

f) Singlera

1165. Dr. Gao testified at trial that Singlera does not have another viable alternative to Illumina’s NGS sequencers for the PanSeer test. (Gao (Singlera) Tr. 2901).
1166. Singlera’s PanSeer test relies on Illumina’s NextSeqDx NGS platform. (Gao (Singlera) Tr. 2875; PX7102 (Gao (Singlera) Dep. at 26)).
1167. Singlera also uses Illumina’s MiSeq sequencer as part of its efforts to develop the PanSeer test. (Gao (Singlera) Tr. 2929).

- 1168. Singlera’s Co-founder, Gary Gao, testified at trial that Singlera’s use of Illumina’s sequencer is “an essential step” in the PanSeer test. (Gao (Singlera) Tr. 2892-93).
- 1169. Dr. Gao testified that Singlera uses Illumina’s sequencer because “[i]t’s very cost-effective, first, and very eas[y to] use, and they are very reliable, and it’s performing in the market.” (Gao (Singlera) Tr. 2894).
- 1170. Dr. Gao explained that Singlera runs its cancer screening test on Illumina’s NGS sequencing platform, in part, because it is “easy to use, very accurate, easy to maintain, and cost effective.” (PX7102 (Gao (Singlera) Dep. at 27-28)).
- 1171. Dr. Gao testified that Singlera runs the PanSeer test on Illumina’s NextSeq Dx sequencer “[b]ecause NextSeq is FDA-cleared, and we have to use FDA-cleared device for FDA trial.” (Gao (Singlera) Tr. 2930-31).
- 1172. Singlera’s Dr. Gao explained that Singlera chose to use Illumina’s NextSeqDx NGS sequencer to develop its cancer screening test because “the NextSeqDx is FDA cleared, and it’s very cost economic” in terms of the number of reads per run. (PX7102 (Gao (Singlera) Dep. at 27)).
- 1173. Singlera’s Dr. Gao testified that, “Illumina has the highest throughput[.]” (PX7042 (Gao (Singlera) IHT at 43)).
- 1174. Dr. Gao described Singlera’s relationship with Illumina as like being a “prisoner of war.” (PX7042 (Gao (Singlera) IHT at 88)).
- 1175. Dr. Gao testified that Oxford Nanopore’s long-read sequencer is not a viable option for Singlera’s Panseer test. (PX7042 (Gao (Singlera) IHT at 66)).
- 1176. Singlera plans to run the PanSeer test on Illumina’s NovaSeq sequencer when the sequencer obtains FDA clearance. (Gao (Singlera) Tr. 2930).

g) Helio

- 1177. Dr. Chahine testified at trial that the Illumina platform is “by far [ ] the preferred one that’s used even at third-party shops” and the “leading one for many different [ ] reasons.” (Chahine (Helio) Tr. 1044).
- 1178. [REDACTED] } (Chahine (Helio) Tr. 1114-15 (*in camera*)).
- 1179. Dr. Chahine testified at trial that Illumina is the preferred NGS platform because “from a business standpoint [ ] it is just considered the top technology with respect to its ability to sequence [ ] accurately . . . at larger scales” that create “some [very useful] economies of scale.” (Chahine (Helio) Tr. 1044).

- 1180. Dr. Chahine testified at trial that Illumina’s suite of NGS sequencers is “designed to sort of scale with the company” and “almost everyone would likely start off with a smaller machine for some of the research but then eventually[, ] if it was successful and there was enough volume, would move up to the NovaSeq.” (Chahine (Helio) Tr. 1022).
- 1181. In comparing Illumina’s MiSeq to its NovaSeq sequencer, Dr. Chahine testified at trial that “quite simply on a NovaSeq you would be able to in a single run test the DNA of many more individuals than you would for a MiSeq [ ] at least more robustly.” (Chahine (Helio) Tr. 1022). He elaborated that “[i]t’s almost like using a more powerful computer for computing.” (Chahine (Helio) Tr. 1022).
- 1182. Helio currently uses Illumina’s MiSeq sequencer for its Helio Liver test. (Chahine (Helio) Tr. 1010-12). Dr. Chahine testified Helio uses the MiSeq because “a smaller machine is more efficient” as a “company in its early stage” prior to “ramp[ing] up.” (Chahine (Helio) Tr. 1012).
- 1183. Dr. Chahine testified at trial that “almost everyone would likely start off with a smaller machine for some of the research but then eventually, you know, if it was successful and there was enough volume, would move up to a NovaSeq.” (Chahine (Helio) Tr. 1022.)
- 1184. Dr. Chahine testified at trial that Illumina’s NovaSeq sequencer “provides economies of scale that are advantageous” because of its capacity to sequence more samples at once. (Chahine (Helio) Tr. 1022-23).
- 1185. Helio has not seriously considered switching from Illumina’s NGS platform to an NGS platform sold by another vendor. (Chahine (Helio) Tr. 1043-44).
- 1186. Helio also purchases NGS sequencers and reagents from Illumina. (Chahine (Helio) Tr. 1024).
- 1187. Helio cannot buy reagents from another company for use on Illumina’s NGS sequencers. (Chahine (Helio) Tr. 1024).
- 1188. Dr. Chahine testified at trial that Illumina’s NGS sequencers and its reagents are a “razor-razorblade model” and the Illumina reagents that Helio purchases “are specific to Illumina.” (Chahine (Helio) Tr. 1024).
- 1189. Dr. Chahine testified that Helio has “looked at different providers. I don’t want to say technically we couldn’t, but the truth is that the entire category uses Illumina. We’re very familiar with Illumina. ... The cost is much lower. ... [T]here are just a number of ... technical advantages and just performance.” (PX7077 (Chahine (Helio) Dep. at 26)).

h) [REDACTED]

1190. [REDACTED]



1191. [REDACTED]

1192. [REDACTED]

1193. [REDACTED]

1194. [REDACTED]

1195. [REDACTED]

1196. [REDACTED]

1197. [REDACTED]

1198. [REDACTED]

1199. [REDACTED]

1200. [REDACTED]

**3. Illumina Understands That Its NGS Platforms Far Surpass Other Platforms on High Throughput, High Accuracy, and Low Cost**

1201. When speaking to investors about the Grail acquisition announcement, Mr. deSouza said, “This [acquisition] is about accessing the largest opportunity in clinical genomics... we have enabled this market, and now we are moving more firmly into the application layer.” (PX2575 (Illumina) at 019 (Illumina, Investor Call Transcript, Sept. 21, 2020)).

1202. [REDACTED] (PX6069 (Illumina) at 15-16 (RFA No. 17) (Illumina Responses & Objections to FTC Requests for Admissions)).

1203. [REDACTED]  
[REDACTED]  
(PX6069 (Illumina) at 16 (RFA No. 18) (Illumina Responses & Objections to FTC Requests for Admissions (*in camera*))).

1204. Respondents' expert, Dr. Carlton notes in his report, [REDACTED]  
[REDACTED] } (RX3864 (Carlton Rebuttal Report) ¶ 24 (*in camera*) (citing PX6090 (Scott Morton Report) ¶ 152 (*in camera*))).

1205. [REDACTED] } (PX2169 (Illumina) at 016 (Illumina, Strategic Plan 2021-2025, Oct. 23, 2020 (*in camera*))).

{

[REDACTED]

}

1206. [REDACTED] } (PX2169 (Illumina) at 020 (Illumina, Strategic Plan 2021-2025, Oct. 23, 2020 (*in camera*))).

1207. [REDACTED] } (PX5026 (Illumina) at 005 (FY20-25 Strategic Plan Initial Revenue Discussion, Jun 4, 2020 (*in camera*))).

**4. Other Industry Participants Recognize that Illumina NGS Platforms Are the Only Viable Option for MCED Testing**

1208. Dr. Vogelstein testified that “[t]he only technology available for short-read sequencing that is at a throughput and cost that would enable liquid biopsy to be analyzed is sold by Illumina.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 67)).
1209. The Illumina NGS sequencer is the only sequencer that can be used for applications that demand “high accuracy for low frequency events” such as multi-cancer early detection. (PX7075 (Stahl (Invitae) Dep. at 71)).
1210. Invitae represented to investors in its Form 10-Q filed with the Securities and Exchange Commission that “[w]e rely on Illumina as the sole supplier of next generation sequencers and associated reagents” and “[i]n the case of an alternative supplier for Illumina, we cannot assure you that replacement sequencers and associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations.” (PX0158 at 51-52 (Invitae Form 10-Q, Nov. 5, 2020)).
1211. Invitae represented to investors in its Form 10-Q filed with the Securities and Exchange Commission that:

ArcherDX’s product customers are required to use Illumina sequencers and reagents .... ArcherDX’s failure to maintain a continued supply of the sequencers and reagents ... would adversely impact its business, financial condition, and results of operations. In particular, while ArcherDX is seeking to validate its tests on additional sequencing platforms, it has not, to date, validated any alternative sequencing platform on which its testing could be run in a commercially viable manner.

(PX0158 at 70 (Invitae Form 10-Q, Nov. 5, 2020)).

**E. NON-ILLUMINA NGS PLATFORMS DO NOT MEET THE REQUIREMENTS OF MCED TESTS**

**1. Thermo Fisher Is Not an Option for MCED Test Developers**

a) Thermo Fisher Recognizes That Its NGS Platform Does Not Meet the Requirements of MCED Tests

1212. Thermo Fisher Vice President of Product Management, Dr. Andrew Felton, testified at trial that Thermo Fisher sequencers are not currently being used for MCED tests. (Felton (Thermo Fisher) Tr. 1987).
1213. Dr. Felton testified that Illumina’s NGS sequencers are better suited than Thermo Fisher’s NGS sequencers for “any application that requires a very large number of samples ... like early cancer detection.” (Felton (Thermo Fisher) Tr. 2001).

1214. According to Dr. Felton, Illumina’s NovaSeq platform has much higher output than any of Thermo Fisher’s NGS sequencers. (Felton (Thermo Fisher) Tr. 2000).
1215. Thermo Fisher’s highest throughput sequencer, the GeneStudio S5, has a maximum output of 130 million reads per run. (Felton (Thermo Fisher) Tr. 1983-84).
1216. According to Dr. Felton, the total work flow time for the GeneStudio to achieve 130 million reads per run is 24 to 48 hours. (Felton (Thermo Fisher) Tr. 1985).
1217. Dr. Felton testified that even Thermo Fisher’s highest throughput sequencer, the GeneStudio, is not an option for MCED developers because “a platform with considerable more out-put per run than 130 million reads would be . . . preferred. . . . In general, the system isn’t well suited to a kind of test that needs a very large number of samples . . . running through it very quickly.” (Felton (Thermo Fisher) Tr. 1987-89).
1218. No other NGS platform available in the United States, other than Illumina’s sequencers, can read more than 130 million fragments per run. (Felton (Thermo Fisher) Tr. 1985).
1219. The cost per read of Thermo Fisher’s GeneStudio is higher than the cost per read of the NovaSeq. (Felton (Thermo Fisher) Tr. 2000).
1220. [REDACTED] (Felton (Thermo Fisher) Tr. 2008) (*in camera*)).
1221. [REDACTED] } (Felton (Thermo Fisher) Tr. 2006) (*in camera*)).
1222. [REDACTED] (PX7097 (Felton (Thermo Fisher) Dep. at 29) (*in camera*)).
1223. [REDACTED] (PX7097 (Felton (Thermo Fisher) Dep. at 34-35) (*in camera*)).
1224. [REDACTED] (PX7097 (Felton (Thermo Fisher) Dep. at 42-43) (*in camera*)).
1225. Dr. Felton, admitted that Thermo Fisher’s NGS platforms are not used for MCED tests because “the implementation of such a test is likely favored to a very high throughput

system in a centralized facility, and our systems are generally suited to . . . smaller amounts of patient samples.” (PX7070 (Felton (Thermo Fisher) IHT at 52-53)).

1226. Mr. Felton explained, “the systems that [Thermo Fisher’s] Ion Torrent provides are generally much better suited to the population of patients who’s progressed to a late-stage cancer setting, so the number of patients is much smaller relative to the number of patients you are screening in a population-screening experiment or study.” (PX7070 (Felton (Thermo Fisher) IHT at 52-53)).

1227. Mr. Felton maintained that [REDACTED] [REDACTED] } (PX7070 (Felton (Thermo Fisher) IHT at 69) (*in camera*)).

1228. Mr. Felton stated further, “we are playing in the late-stage cancer setting. The GRAIL Illumina combination would be playing in the early cancer” setting. (PX7070 (Felton (Thermo Fisher) IHT at 69)).

b) [REDACTED]

1229. [REDACTED] } (Chudova (Guardant) Tr. 1218-19) (*in camera*) [REDACTED] }.

1230. [REDACTED] } (Chudova (Guardant) Tr. 1218-19) (*in camera*)).

1231. [REDACTED] (Chudova (Guardant) Tr. 1219-20) (*in camera*)).

1232. [REDACTED] } (Chudova (Guardant) Tr. 1218-19) (*in camera*)).

1233. [REDACTED] (Chudova (Guardant) Tr. 1220) (*in camera*)).

1234. [REDACTED] (Chudova (Guardant) Tr. 1220) (*in camera*)).

1235. [REDACTED]

[REDACTED]

(PX7045 (Chudova (Guardant) IHT at 49-50) (*in camera*)).

1236. Guardant’s Mr. Getty testified at trial that Guardant cannot run its MCED test on a Thermo Fisher sequencer. (Getty (Guardant) Tr. 2688).

1237. Freenome evaluated Illumina’s sequencer against Thermo Fisher’s S5 sequencer. (Nolan (Freenome) Tr. 2715-18).

1238. Mr. Nolan testified that Illumina’s sequencer “did a better job with [sequence] variant calling” and “did a better job of detecting [colorectal cancer]” than Thermo Fisher’s S5 sequencer in Freenome’s evaluation. (Nolan (Freenome) Tr. 2715-16).

1239. Freenome’s Nolan testified that { [REDACTED] } (PX7094 (Nolan (Freenome) Dep. at 222-223) (*in camera*)).

1240. Freenome’s Nolan testified that [REDACTED] (PX7050 (Nolan (Freenome) IHT at 100-01) (*in camera*)).

1241. Freenome’s Otte testified that { [REDACTED] }

[REDACTED]

(PX7055 (Otte (Freenome) IHT at 65-66) (*in camera*)).

1242. Freenome’s Otte testified, { [REDACTED] } (PX7055 (Otte (Freenome), IHT at 66) (*in camera*)).

1243. Thermo Fisher’s Dr. Felton testified that [REDACTED] (Felton (Thermo Fisher) Tr. 2006-2007 (*in camera*)).

1244. Dr. Felton explained { [REDACTED] } [REDACTED]  
[REDACTED]  
(PX7070 (Felton (Thermo Fisher) IHT at 58-59) (*in camera*)).

1245. Singlera Co-founder, Gary Gao, testified that Thermo Fisher is one of the alternatives to Illumina that Singlera has evaluated. (Gao (Singlera) Tr. 2894).

1246. Dr. Gao testified at trial that Thermo Fisher is “not going to be a viable alternative” for its PanSeer test and it has no plans to switch to Thermo Fisher’s NGS platform. (Gao (Singlera) Tr. 2894).

1247. Singlera’s Dr. Gao testified that Thermo Fisher’s platforms are “not cost-effective,” “not an easy workflow,” and “not basically a viable alternative to Illumina[‘s] platform.” (PX7042 (Gao (Singlera) IHT at 42-43)).

1248. Dr. Gao indicated that the throughput of Illumina’s NextSeqDx instrument is higher than the Thermo Proton instrument: “[A] NextSeqDx will produce you about a -- I think between 100 to 300 million read per run while the Thermo Proton is more like 40 million to 100 million, so it’s about only one-third to one-fifth of what Illumina produce.” (PX7042 (Gao (Singlera) IHT at 43)).

1249. In characterizing Thermo Fisher’s NGS platform, Singlera’s Gao testified:  
  
[T]here are basically sequencing -- higher sequencing error and a sequencing bias with the Thermo technology. For example, the homopolymer problem is significant in the Ion platform from Thermo Fisher, but the Illumina doesn’t have that shortcoming. And also the mutation, you know, the error, sequencing error rate is higher in the Proton system.

(PX7042 (Gao (Singlera) IHT at 44)).

1250. In explaining why Illumina’s FDA-cleared NextSeqDX NGS platform is suitable for Singlera’s PanSEER test and Thermo Fisher’s NGS platform is not, Dr. Gao testified:

[T]he throughput is lower, and you know, it’s only one-third, so you want a -- Illumina system can do three times more sample. For screening, your scale economy coming from you can do many more sample in one day. That will save you equipment cost, you know, your depreciation, your labor, your time, your competitive skill.

(PX7042 (Gao (Singlera) IHT at 53)).

1251. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 103-04) (*in camera*)).

1252. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 106) (*in camera*)).

1253. Dr. Lengauer explained that Thrive’s CancerSeek technology [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 96) (*in camera*)).

1254. Dr. Lengauer testified that [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 96) (*in camera*)).

1255. Dr. Lengauer said [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 107-08) (*in camera*)).

1256. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 107) (*in camera*)).

1257. Dr. Lengauer described [REDACTED]

[REDACTED] }

(PX7051 (Lengauer (Third Rock Ventures) IHT at 108-09) (*in camera*)).



1258. Dr. Lengauer testified that [REDACTED]  
[REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 109) (*in camera*)).
1259. [REDACTED]  
[REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 109-10) (*in camera*)).
1260. [REDACTED]  
[REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 112) (*in camera*)).
1261. Kevin Conroy, CEO of Exact, testified that [REDACTED]  
[REDACTED] (PX7110 (Conroy (Exact) Dep. at 70-71) (*in camera*)).
1262. [REDACTED]  
[REDACTED] } (PX7058 (Conroy (Exact) IHT at 120-21) (*in camera*)).
1263. Mr. Conroy further testified that [REDACTED]  
[REDACTED] (PX7058 (Conroy (Exact) IHT at 70) (*in camera*)).
1264. [REDACTED]  
[REDACTED] } (PX7111 (Fesko (Natera) Dep. at 52-53) (*in camera*)).
1265. [REDACTED]  
[REDACTED] (PX7111 (Fesko (Natera) Dep. at 52-53) (*in camera*)).
1266. Ms. Perettie explained that [REDACTED]  
[REDACTED] (PX7068 (Perettie (FMI-Roche) IHT at 60)).
1267. Invitae's Stahl testified that Thermo Fisher's "sequencer data quality is so far below what Illumina can do, [that] you do not have a viable product" if a cancer screening test is run on Thermo Fisher's NGS platform. (PX7044 (Stahl (Invitae) IHT at 51-53)).
1268. Mr. Stahl explained that Thermo Fisher's error rates are "very high" and "one mistake could mean cancer or not cancer." (PX7044 (Stahl (Invitae) IHT at 92-93)).

## 2. BGI Is Not an Option for MCED Test Developers

### a) Illumina Sued BGI for Patent Infringement and Obtained an Injunction That Bars BGI from Beginning to Sell its NGS Platforms in the United States

1269. BGI is a Chinese genomics company that does next-generation sequencing. (deSouza (Illumina) Tr. 2226).

1270. When Mr. deSouza spoke at the JPM Life Sciences CEO Conference Series and answered questions from investors, one question Mr. deSouza responded to was whether BGI may try to come to the United States that year. (deSouza (Illumina) Tr. 2223-2225; PX2544 (Illumina) at 024-025 (Transcript of JPM Life Sciences CEO Conference Call, Sept. 3, 2019)). Mr. deSouza responded, “We [Illumina] think that every player should be considering coming to the U.S. It’s also an area where we [Illumina] have very strong IP protection. And so for BGI or anyone else to be successful in the U.S., they’ll have to do so with the technology that they have the IP to run.” (deSouza (Illumina) Tr. 2223-2225; PX2544 (Illumina) at 024-025 (Transcript of JPM Life Sciences CEO Conference Call, Sept. 3, 2019)).

1271. As set forth below in Section V.E.2.c., MCED test developers testified that the uncertainty around BGI’s freedom to operate in the United States is one reason BGI is not a viable NGS option for MCED test developers.

1272. As Illumina’s CEO admitted at trial, Illumina has filed multiple lawsuits against BGI alleging that it has infringed on Illumina’s patents. (deSouza (Illumina) Tr. 2226).

1273. An Illumina board presentation states that it “has 11 active IP infringement suits against BGI.” (PX2847 (Illumina) at 013 (Project Protego BoD Discussion, July 15, 2020)).

1274. In 2019 and 2020, Illumina successfully sued BGI in the Northern District of California alleging that “BGI’s sequencers and reagents infringe Illumina owned patents. (PX0119 at 001 (Illumina Inc. Announces that U.S. Federal Court Issues Preliminary Injunction Against BGI Companies)).

1275. Dr. Felton testified that Thermo Fisher and Illumina are the only two companies offering short-read NGS sequencers in the United States. (Felton (Thermo Fisher) Tr. 1996).

### b) Illumina is Already Seeking Additional Injunctive Relief Against BGI Based on U.S. Patents that Do Not Expire Until 2027 and May Assert Additional Patents Against BGI That Run Beyond 2027

1276. Illumina has already filed additional patent infringement claims against BGI. (PX9232 at 015, 025-027 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019)).

1277. Illumina filed claims against BGI in a Delaware Federal Court alleging that BGI infringed Illumina’s U.S. Patent No. 9,303,290, U.S. Patent No. 9,217,178, and U.S. Patent No. 9,970,055. (deSouza (Illumina) Tr. 2226; PX9232 at 015, 025-027 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019)).
1278. Illumina has sought an order preliminarily and permanently enjoining BGI from infringing on its U.S. Patent No. 9,303,290, U.S. Patent No. 9,217,178, and U.S. Patent No. 9,970,055. (PX9232 at 032 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019)).
1279. The latest expiring of these patents, Illumina’s U.S. Patent 9,217,178, does not expire until December 22, 2027. (PX9232 at 053 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019) (patent attached as exhibit showing the Patent Cooperation Treaty filing date of Dec. 13, 2005 and an extension of the twenty year patent term under 35 U.S.C. 154(b) by 739 days)).
1280. Dr. Alex Aravanis, Illumina’s Chief Technology Officer, spoke at an event titled “Baird Non-Deal Roadshow,” a large group investor meeting on Monday, February 22, 2021. (deSouza (Illumina) Tr. 2229-2230; PX2822 (Illumina) at 001 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)).
1281. One question Dr. Aravanis prepared a response to for the “Baird Non-Deal Roadshow” meeting was:
- I’d be really curious to hear about near-term patent expiration. I know there are 3 or 4 expiring in next 2-3 yrs. If we could dig into what those patents cover and how ILMN thinks about the impact of those patents expiring, that would be helpful.
- (deSouza (Illumina) Tr. 2220-2231; PX2822 (Illumina) at 006 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)).
1282. Dr. Aravanis’ prepared response to the question on near-term patent expiration at the Baird Non-Deal Roadshow notes that Illumina has alleged that BGI infringed patents that expire after 2023 and range from 2024 to 2027:
- Illumina also alleged infringement by BGI of a number of other patents in the U.S. and Europe with later expiration dates. These include patents directed to Illumina’s proprietary imaging reagent, modified polymerase and fluorescent dyes, which have expiration dates ranging from 2024 to 2027 depending on the patent and country.
- (deSouza (Illumina) Tr. 2231; PX2822 (Illumina) at 006 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)).
1283. The patents Dr. Aravanis described at the Baird Non-Deal Roadshow include the patents that Illumina has alleged BGI has infringed in the counterclaims BGI filed in Delaware.

(deSouza (Illumina) Tr. 2231; PX9232 at 032 (Answer and Counterclaim, *Complete Genomic, Inc. v. Illumina, Inc.*, Case 1:19-cv-00970-MN (D. Del.) (July 25, 2019)).

1284. Dr. Aravanis’ response further notes that “[a]s we learn more about BGI’s products, additional patents may become relevant” and that Illumina has additional patents touching “every aspect of the sequencing workflow, including nucleotides, enzymes, reagent mixes, instruments, optics, analysis software, and bioinformatics, which result from Illumina’s significant investments in research and development.” (deSouza (Illumina) Tr. 2231-2232; PX2822 (Illumina) at 006-007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)). According to Dr. Aravanis’ response, these additional patents extend from 2023 to beyond 2030. (deSouza (Illumina) Tr. 2232; PX2822 (Illumina) at 006-007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)).
1285. Dr. Aravanis’ notes that, as Illumina continues to innovate, Illumina intends to “broadly file patent applications covering these innovations, providing competitive advantages in our key technology areas.” (deSouza (Illumina) Tr. 2232; PX2822 (Illumina) at 007 (Baird Non-Deal Roadshow with Alex Aravanis, Feb. 19, 2021)).

c) Even if BGI Entered the U.S. Market, the Uncertainty Around BGI’s Freedom to Operate in the United States in the Future Makes MCED Developers Unwilling to Switch to BGI

1286. Mr. Stahl testified that “Illumina has sued BGI for patent infringement. So the technologies are very similar. Due to the risk of that IP and them not being well entrenched [sic] in the US and also not having regulatory clearances in the US, we’ve decided not to pursue that instrument.” (PX7075 (Stahl (Invitae) Dep. at 74-75)).

1287. [REDACTED] } (PX7068 (Perettie (FMI-Roche) IHT at 59-60) (*in camera*)).

1288. [REDACTED] } (PX7068 (Perettie (FMI-Roche) IHT at 64) (*in camera*)).

1289. [REDACTED] } (PX7074 (Perettie (FMI-Roche) Dep. at 158) (*in camera*)).

1290. Dr. Gao testified that using BGI for its PanSeer test is “out of the picture” because of the IP dispute involving its sequencers. (Gao (Singlera) Tr. 2895).

1291. Dr. Gao explained the “BGI platform IP” would expose Singlera to “business risk from a legal point of view”: If Singlera were to “develop a [cancer screening test] depending on

BGI[‘s] . . . sequencer, we spend 40 to 60 million dollar[s] to get FDA approval. If they [BGI] were sued, we cannot use their machine.” (PX7042 (Gao (Singlera) IHT at 63)).

1292. Dr. Gao identified the legal risk that Illumina patents would continue to block BGI as a reason why Singlera would not switch to BGI, stating, “[c]ommercially, [] we don’t know whether [the] BGI machine will be able to continue. Or even if they decided they cannot just – they cannot continue their operation fully, then we are dead. . . . We cannot risk our future on other companies’ legal potential and commercial potential.” (PX7042 (Gao (Singlera) IHT at 63).

1293. [REDACTED]  
[REDACTED] (Rabinowitz (Natera) Tr. 338-341 (*in camera*)).

1294. [REDACTED]  
[REDACTED] } (Rabinowitz (Natera) Tr. 339 (*in camera*)).

1295. [REDACTED]  
[REDACTED] } (Rabinowitz (Natera) Tr. 338 (*in camera*)).

d) Even if BGI Entered the U.S. Market, U.S. Companies Are Unlikely to Use a Chinese Company Due to Data Privacy and Reputational Concerns

1296. BGI is a Chinese company affiliated with the Chinese government. (deSouza (Illumina) Tr. 2312).

1297. [REDACTED] (PX5027 (Illumina) at 063 [REDACTED] (*in camera*)).

1298. Illumina’s Senior Director of Corporate Strategy circulated a “Sample of 2020 BGI Headlines” that includes, among other things, “IP violations” headlines and “Ethics issues” headlines such as “Chinese coronavirus test maker [BGI] agreed to build a Xinjiang gene bank,” and “Commerce Department Adds Eleven Chinese Entities Implicated in Human Rights Abuses in Xinjiang to the Entity List.” (PX2170 (Illumina) at 001-002 (Email from J. Andrew, Illumina, to E. Milsovic, Illumina, Nov. 2, 2020)).

1299. [REDACTED] } (PX2790 (Illumina) at 001 (Email from J. Andrew, Illumina, to J. Goswami, Illumina, Jan. 29, 2021) (*in camera*)).

1300. [REDACTED] } (PX2791 (Illumina) at 001 (Email from J. Andrew, Illumina, to F. deSouza et al., Illumina, Jan. 30, 2021) (*in camera*)).

1301. Dr. Aravanis testified that:

[T]here have been some concerns raised about the privacy and data integrity of data produced on the BGI system and whether or not that data would be protected . . . for its customers . . . [such as] data from the instruments, you know, being sent to China, perhaps without customers' knowledge.

(PX7065 (Aravanis (Illumina) IHT at 156)).

1302. Mr. Stahl testified that there is a “broader macro question” about using BGI machines “in the sense that [BGI is] a Chinese company and US-China relations aren't the greatest, so to be determined.” (PX7075 (Stahl (Invitae) Dep. at 99)).

1303. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 132) (*in camera*)).

1304. [REDACTED] } (Chahine (Helio) Tr. 1048 (*in camera*)).

1305. [REDACTED] (Chahine (Helio) Tr. 1059-1060 (*in camera*)).

1306. [REDACTED] (Chahine (Helio) Tr. 1110 (*in camera*)).

1307. Helio's Chinese and United States operations share a “common interest and strategies,” but the R&D is completely segregated between the two operations—all of the R&D work in China is done with Chinese samples, sequenced in China, and developed with an algorithm specific to China. (Chahine (Helio) Tr. 1026).

1308. Dr. Chahine testified at trial that Helio has chosen to segregate the R&D between its United States and Chinese operations because of “specific laws” and because it “makes good business sense to completely segregate and not commingle any of those data” between the operations. (Chahine (Helio) Tr. 1026).
1309. [REDACTED] }  
(Chahine (Helio) Tr. 1048-49 (*in camera*)).
1310. [REDACTED] } (Chahine (Helio) Tr. 1048-50 (*in camera*)).
1311. [REDACTED] } (Chahine (Helio) Tr. 1048-49 (*in camera*)).
1312. [REDACTED] (Rabinowitz (Natera) Tr. 338-341 (*in camera*)).
1313. [REDACTED] (Rabinowitz (Natera) Tr. 338-41 (*in camera*)).
1314. [REDACTED] } (Rabinowitz (Natera) Tr. 338-341 (*in camera*)).
1315. [REDACTED] (PX7058 (Conroy (Exact) IHT at 122-123) (*in camera*)).
1316. [REDACTED] (PX7058 (Conroy (Exact) IHT at 122-123) (*in camera*)).
1317. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 122-123) (*in camera*)).
1318. Though both BGI and Singlera have Chinese offices, Dr. Gao testified that “may not be beneficial for [BGI] for [Singlera] to be Chinese, because we kind of know them better, you know, then in terms of business practice, reputation.” (PX7042 (Gao (Singlera) IHT at 61-62)).
1319. Dr. Gao testified that BGI’s reputation is “[n]ot great.” (PX7042 (Gao (Singlera) IHT at 62)).

1320. [REDACTED] } (PX5027 (Illumina) at 057  
(in camera)).

1321. [REDACTED] (PX5027 (Illumina) at 058 (in  
camera)).

1322. [REDACTED] (PX5027 (Illumina) at 058  
(in camera)).

1323. [REDACTED] (PX5027 (Illumina) at 058 (in  
camera)).

1324. [REDACTED] } (PX5027 (Illumina) at 058 (in  
camera)).

e) Even if BGI Entered the U.S. Market, MCED Test Developers Do Not Consider BGI an Alternative to Illumina

1325. [REDACTED] (Chahine (Helio) Tr. 1048 (in camera)).

1326. [REDACTED] } (PX7077 (Chahine (Helio) Dep. at 28) (in camera)).

1327. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 240 (in camera)).

1328. [REDACTED] (PX7051  
(Lengauer (Third Rock Ventures) IHT at 114) (in camera)).

1329. [REDACTED] } (PX7051  
(Lengauer (Third Rock Ventures) IHT at 114) (in camera)).



1330. [REDACTED]  
[REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 113-115) (*in camera*)).

1331. [REDACTED] } (Rabinowitz (Natera) Tr. 341 (*in camera*)).

1332. [REDACTED]  
[REDACTED] (Rabinowitz (Natera) Tr. 341 (*in camera*)).

1333. [REDACTED]  
[REDACTED] } (Rabinowitz (Natera) Tr. 337-338 (*in camera*)).

1334. [REDACTED]  
[REDACTED] } (Rabinowitz (Natera) Tr. 337-338 (*in camera*)).

1335. [REDACTED]  
[REDACTED] } (Rabinowitz (Natera) Tr. 338-341 (*in camera*)).

1336. [REDACTED]  
[REDACTED] (Rabinowitz (Natera) Tr. 360-361 (*in camera*)).

1337. [REDACTED]  
[REDACTED] } (Rabinowitz (Natera) Tr. 342 (*in camera*)).

1338. [REDACTED]  
[REDACTED] } (Rabinowitz (Natera) Tr. 342-343 (*in camera*)).

1339. [REDACTED]  
[REDACTED] (Rabinowitz (Natera) Tr. 361 (*in camera*)).

1340. [REDACTED]  
[REDACTED] } (Rabinowitz (Natera) Tr. 341-342 (*in camera*)).

1341. [REDACTED] } (Rabinowitz (Natera) Tr. 338-341 (*in camera*)).
1342. Dr. Gao explained at trial that “[a]ll we hear is [that BGI’s] platform [is] not very reliable. Breakdown may be frequently, and the service is not that good, so . . . [that is what] I hear from market.” (Gao (Singlera) Tr. 2899).
1343. Dr. Gao testified that BGI has a reputation for being “spotty, not as good as Illumina.” (Gao (Singlera) Tr. 2898).
1344. Dr. Gao testified that BGI’s poor reputation for reliability and service prevents Singlera from using BGI sequencers to run its PanSeer test. (Gao (Singlera) Tr. 2899).
1345. [REDACTED] } (PX5027 (Illumina) at 058 (*in camera*)).

**3. “Extremely Inefficient” Long-Read NGS Is Not an Option for MCED**

a) Industry Participants and the Parties Recognize that Long-Read NGS is Not an Option for MCED

1346. Illumina’s CEO, Mr. deSouza, stated on his JP Morgan investor call that long-read platforms such as PacBio will not expand into short read NGS for oncology applications. (*See* PX2544 (Illumina) at 027 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching “JPM Life Sciences CEO Conference Call Series” transcript, Sept. 5, 2019) (“And so if we look at how this industry plays out over the next decade, we expect to continue to see that dynamic play out where there are applications for long-read that will continue to scale. And as those vendors continue to drive the price points down as they expand their accuracy as PacBio has done, it’ll catalyze the adoption and the expansion of those markets but it won’t get them into the short-read technology of markets like NIPT or oncology that we expect to be competing into the next decade.”).
1347. PacBio supplies long-read NGS platforms, and its 2020 annual revenue was approximately \$79 million. (PX8399 (Henry (PacBio) Decl. ¶ 1)).
1348. Long-read NGS platforms “can generate contiguous reads of up to 25,000 base pairs” in contrast to short-read NGS platforms like Illumina’s that generate contiguous reads of only approximately 700 base pairs. (PX8399 (Henry (PacBio) Decl. ¶ 3)).
1349. Former Illumina CFO/COO and current PacBio CEO Christian Henry explained: “To accomplish whole-genome sequencing, sequencing platforms must sequence longer genomes—such as the human genome—by piecing together many individual sequencing reads using bioinformatics software. This process is akin to putting together puzzle pieces to form a complete picture of a genome.” (PX8399 (Henry (PacBio) Decl. ¶ 2)).

1350. Mr. Henry explained that long-read NGS platforms “are particularly beneficial for applications like whole-genome sequencing because it is easier to determine the entire genomic sequence by assembling fewer long sequence fragments than by assembling many short ones. Using the puzzle analogy, it is easier to piece together a puzzle with fewer larger pieces than many smaller ones.” (PX8399 (Henry (PacBio) Decl. ¶ 3)).

1351. Mr. Henry declared that, “[b]ecause [ctDNA fragments] are typically fewer than 350 base pairs long, Illumina’s short-read NGS platforms are capable of analyzing many ctDNA fragments in their entirety.” (PX8399 (Henry (PacBio) Decl. ¶ 5)).

1352. Mr. Henry indicated that, “[g]iven the relatively short length of many ctDNA fragments, long-read sequencing does not often present the same technical benefits over short-read sequencing as it does for other sequencing applications.” (PX8399 (Henry (PacBio) Decl. ¶ 5)).

1353. [REDACTED]  
 (PX8399 (Henry (PacBio) Decl. ¶ 5) (*in camera*)).

1354. [REDACTED] (PX8399 (Henry (PacBio) Decl. ¶ 5) (*in camera*)).

1355. [REDACTED] (PX8399 (Henry (PacBio) Decl. ¶ 9) (*in camera*)).

1356. [REDACTED] (PX8399 (Henry (PacBio) Decl. ¶ 10) (*in camera*)).

1357. Illumina’s CEO Francis deSouza explained in an investor call that in looking at circulating tumor DNA fragments, “the ability to do very long-read doesn’t offer any incremental value and certainly isn’t worth paying a significant premium in terms of the cost per base.” (PX2544 (Illumina) at 026-027 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching “JP Morgan Life Sciences CEO Conference Call Series” transcript, Sept. 5, 2019)).

1358. Illumina’s Mr. deSouza, explained to investors that short-read NGS platforms are much more suitable for detecting ctDNA fragments than long-read platforms:

The way we see it is that there are applications that are very well suited for long-read technology, that frankly short-read technology don’t [sic] address and vice versa it’s true as well. But there are markets, our core markets where short-read

technologies work exceptionally well and long-read don't offer any additional values. So let me give you some specifics. If you look at some of our core markets, for example, in NIPT the fragments we're looking at are 150-ish base pairs. So somewhere between 130 base pairs and maybe up to 200 base pairs long. And so the ability to sequence fragments that are a million base pairs long or a hundred thousand base pairs long is frankly irrelevant, because the fragments are nowhere near that long. And so what customers are looking for is a high-volume sequencer that's able to cost effectively and accurately read those short fragments. That's true in circulating tumor DNA fragments in the oncology space as well. And so if you look at the number of our core markets, the ability to do very long-read doesn't offer any incremental value and certainly isn't worth paying a significant premium in terms of the cost per base.

(PX2544 (Illumina) at 026-027 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching "JP Morgan Life Sciences CEO Conference Call Series" transcript, Sept. 5, 2019)).

1359. Illumina's Mr. deSouza, explained to investors that long-read NGS platforms are not likely to impact Illumina's market position for liquid biopsy applications:

Our thoughts on long read haven't really changed in the sense that ... we believe long-read technologies ... serve about 5% of the market where you're doing de novo sequencing for new species, for example. ... [F]or the vast majority of the market, the 95% of the market, short reads are just simply the better technology in terms of accuracy, in terms of price performance. The price gap can be 10x between what you can do in short reads and what you can do in long reads. The raw accuracy is [ ]higher on short reads. ... [In markets like] liquid biopsy [ ] [y]ou're looking at fragments that are under 200 base pairs long. And so, you're not willing to make a trade-off in accuracy or cost just to be able to read 10,000 base pairs.

(PX2622 (Illumina) at 012 (Email from J. Cunningham, Illumina, to F. deSouza, Illumina, attaching "Edited Transcript, ILMN.OQ – Illumina Inc. at JPMorgan Healthcare Conference (Virtual) and Q&A Session," , Jan. 12, 2021)).

1360. In discussing Oxford Nanopore's long-read sequencing platform, Illumina Senior Vice President and Chief Technology Officer, Alex Aravanis, described Illumina as "superior in a meaningful way . . . around data accuracy, so the accuracy of the Oxford Nanopore reads is not as good as the Illumina reads." (PX7065 (Aravanis (Illumina) IHT at 157-59) (noting that MCED tests other than Grail are even more sensitive to NGS accuracy)).
1361. Thermo Fisher Vice President of Product Management Andrew Felton testified that "it's highly inefficient to use a platform [for routine testing applications] that can generate and has to generate very long reads compared to a platform that's ... primary utility is in the 200 to 600 base pair read length space." (Felton (Thermo Fisher) Tr. 1997-1998).

1362. Mr. Felton explained that the cost of clinical oncology sequencing “would tend to be higher [for long read NGS instruments] because you typically have smaller numbers of reads of longer reads in the long-read technologies. (PX7070 (Felton (Thermo Fisher) IHT at 24-25)).
1363. Mr. Felton testified that when short-read NGS instruments are used in clinical oncology, “your cost per read and naturally your cost per [gigabase] of sequence would tend to be much lower than for a long-read technology.” (PX7070 (Felton (Thermo Fisher) IHT at 24-25)).
1364. Dr. Bert Vogelstein of Johns Hopkins University testified that “[l]ong-read sequencers are [ ] unsuited for early detection [cfDNA] liquid biopsy testing” in part because “the throughput of long-read sequencers are much lower than the throughput of short-read sequencers” and “the error rates of long-read sequencers are much too high to effectively analyze the molecules and plasma”. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).
1365. Dr. Vogelstein testified that long-read sequencing technologies “are not applicable to the analysis of plasma DNA,” and he elaborated “the reason is simple to understand: Plasma DNA is not long. Plasma DNA, the average size in a normal individual is 167 base pairs. And in cancers, it’s a bit shorter.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 73-74)).
1366. Dr. Vogelstein testified that “long-read sequencing is not suitable for analyzing the plasma DNA molecules that” his lab tests in part because “the throughput of long-read sequencers are much lower than the throughput of short-read sequencers” and “[a]s a result, short-read sequencers can analyze the plasma DNA molecules much faster and in many more samples in a given time than can long-read sequencers”. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).
1367. Dr. Vogelstein testified that long-read sequencing is not suitable for analyzing plasma DNA molecules in part because “the error rates of long-read sequencers are much too high to effectively analyze the molecules and plasma for [ ] early cancer detection with the number of artifactual mutations outnumbering the expected number of real mutations by many fold.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).
1368. Dr. Vogelstein testified that PacBio’s sequencers are not “applicable to a good assay for plasma.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 73-74)).
1369. Dr. Vogelstein testified that “only short-read sequencing is suitable for the liquid biopsy sequencing” that his lab performs for the research it conducts. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 65-66)).

b) MCED Test Developers Testified that Long-Read NGS Is Not an Alternative to Illumina NGS

1370. [REDACTED]

[REDACTED] } (Chudova (Guardant) Tr. 1221-22) (*in camera*)).

1371. [REDACTED]  
[REDACTED] (Chudova (Guardant) Tr. 1218-19) (*in camera*)).

1372. [REDACTED]  
[REDACTED] } (Chudova (Guardant) Tr. 1218-19) (*in camera*)).

1373. [REDACTED]  
[REDACTED] (Chudova (Guardant) Tr. 1223-24) (*in camera*)).

1374. [REDACTED]  
[REDACTED] } (Chudova (Guardant) Tr. 1224 (*in camera*)).

1375. Guardant Senior Vice President of Technology Dr. Darya Chudova explained that because ctDNA fragments are short in length, “mostly below 400 base pairs in length,” and there is “nothing to read beyond the molecule itself ... it’s not useful to have long-read technology[]” for MCED tests. (PX7100 (Chudova (Guardant) Dep. at 73)).

1376. [REDACTED]  
[REDACTED] } (PX7045 (Chudova (Guardant) IHT at 44-47, 48-49) (*in camera*)).

1377. [REDACTED]  
[REDACTED]

[REDACTED]

(PX7045 (Chudova (Guardant) IHT at 47-48) (*in camera*)).

1378. [REDACTED]

[REDACTED]

(PX7045 (Chudova (Guardant) IHT at 48-49) (*in camera*)).

1379. [REDACTED] } (Conroy (Exact) Tr. 1759) (*in camera*)).

1380. [REDACTED] } (Conroy (Exact) Tr. 1759) (*in camera*)).

1381. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 180-81 (*in camera*)).

1382. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 117) (*in camera*)).

1383. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 117) (*in camera*)).

1384. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 117) (*in camera*)).

1385. [REDACTED]

[REDACTED]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 116-17) (*in camera*)).

1386. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 107-09 (*in camera*)).

1387. [REDACTED] } (PX7055 (Otte (Freenome) IHT at 64-66) (*in camera*)).

1388. [REDACTED] (PX7055 (Otte (Freenome) IHT at 72) (*in camera*)).

1389. [REDACTED]

(PX7055 (Otte (Freenome) IHT at 72-73) (*in camera*)).

1390. [REDACTED] (PX7055 (Otte (Freenome) IHT at 18) (*in camera*)).



1391. Singlera Co-founder and former CEO Dr. Gary Gao testified at trial that long read sequencing technology is not a viable option for the PanSeer test. (Gao (Singlera) Tr. 2900-01).
1392. At trial, Dr. Gao explained that long read sequencers are prohibitively expensive compared to Illumina’s sequencers for the PanSeer test. (Gao (Singlera) Tr. 2900-01).
1393. Dr. Gao further explained at trial, “Illumina, like I said, even the small NextSeq Dx can carry 200 to 400 million read per run, and the long reader can only carry the millions of reads. . . . The cost will be much higher when we use it for cancer detection.” (Gao (Singlera) Tr. 2901).
1394. [REDACTED] (PX7111 (Fesko (Natera) Dep. at 55-56) *(in camera)*).
1395. [REDACTED] (PX7074 (Perettie (FMI-Roche) Dep. at 157) *(in camera)*).
1396. Helio Health CEO Dr. Kenneth Chahine testified that long-read NGS platforms “provid[e] information that today we don’t believe is important. And so if you are going to ... pay additional money for it ... it doesn’t make sense for us to do that to date.” (PX7077 (Chahine (Helio Health) Dep. at 28)).
1397. Invitae’s President of Oncology Joshua Stahl explained that long read sequencers have a low throughput so “you can’t do applications like ctDNA” which require many reads of each sequence. (PX7044 (Stahl (Invitae) IHT at 97-100)).
1398. Invitae’s Mr. Stahl testified that that long-read sequencing provider Oxford Nanopore’s “error rates are high, higher than [Thermo Fisher’s] Ion Torrent and their throughput ... is very low and so it’s not a practical sequencing instrument within the precision oncology space.” (PX7075 (Stahl (Invitae) Dep. at 74)).

**F. OTHER TESTING TECHNOLOGIES ARE NOT VIABLE SUBSTITUTES FOR NGS FOR MCED TESTS**

1399. In a 2019 presentation discussing a combined Illumina-Grail entity, Illumina stated that “[n]o technology has demonstrated the ability to achieve the required analytical sensitivity of 0.01% of ctDNA from a couple of blood tubes worth of input. [Illumina’s] hypothesis is that deeper sequencing (breadth and depth) will drive higher sensitivity and specificity than lower resolution methods like digital PCR and lower coverage WGS, which will be critical to performance in screening. Specifically, deeper sequencing allows more coverage of cancer relevant genes and deeper sampling of the ctDNA to find rare molecules.”

(PX2712 (Illumina) at 027 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, attaching Python: A Revolution in Early Cancer Detection Presentation, Dec. 3, 2019)).

1400. Illumina materials state that no other DNA analysis technology can analyze as many DNA fragments as NGS or characterize almost all biomarkers contained within each fragment like NGS. (See PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR) (“ . . . qPCR can only detect known sequences. In contrast, NGS is a hypothesis-free approach that does not require prior knowledge of sequence information.”); see also PX7097 (Felton (Thermo Fisher) Dep. at 39) (testifying that PCR is generally not used to detect unknown variants)).
1401. Illumina Senior VP of Corporate Development and Strategic Planning, Joydeep Goswami, explained, “NGS is a great solution” for applications like cancer screening because “cancer is by definition a disease that manifests due to changes in DNA” and “NGS helps customers assess the . . . changes in DNA . . . very, very quickly and comprehensively.” (PX7087 (Goswami (Illumina) Dep. at 100-01)).
1402. Dr. Felton testified that multi-cancer early detection is an application suited for high-throughput NGS sequencers because “[t]he collection of samples from a wide area of the population is inherently easier if it’s funneled into a central facility . . . and then running those samples on a high throughput platform would reduce the amount of labor time involved in the processing of said samples.” (Felton (Thermo Fisher) Tr. at 2002).
1403. [REDACTED] (PX7055 (Otte (Freenome) IHT at 63) (*in camera*)).
1404. [REDACTED] (PX7100 (Chudova (Guardant) IHT at 20) (*in camera*)).
1405. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 183 (*in camera*)).
1406. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 268-70 (*in camera*)).

**1. Microarray Platforms**

1407. Microarrays test DNA fragments for the presence of predefined target sequences. (PX7072 (deSouza (Illumina) IHT at 55; PX7070 (Felton (Thermo Fisher) IHT at 20-21)).
1408. Microarrays determine whether specific sequences are present within a sample. (PX7070 (Felton (Thermo Fisher) IHT at 20-21) (“Q At a high level, what is the difference between

Thermo's NGS business and its microarray business? A The microarray technology provides for so-called hypothesis-based experiments primarily for gene expression, genotyping, and copy. By that we mean, you have to know something about the sequences that you're trying to interrogate to place them onto the array to be detected; whereas, next-generation sequencing is a so-called hypothesis-free technology in which you do not have to understand the sequences that you are trying to interrogate. You just sequence them directly.")).

- 1409. A microarray is a device "that [labs] can hybridize DNA onto, and the device fluoresces, indicating what DNA is present..." (PX7113 (Rabinowitz (Natera) Dep. at 114)).
- 1410. Microarrays do not provide precise readouts of the sequence of nucleotides contained within fragments of DNA. (Chudova (Guardant) Tr. 1177).
- 1411. Microarray technology has a lower throughput than NGS. (Felton (Thermo Fisher) Tr. 1992-1993).
- 1412. NGS is better suited than microarray for "more things like oncology testing, inherited disease testing where ... you're looking to detect a relatively reasonable number of mutations, but across a large genomic footprint. That would tend to be the space that [NGS platform instruments] would have an advantage over a microarray platform." (Felton (Thermo Fisher) Tr. 1993).
- 1413. Microarrays do not provide the level of accurate quantification that is possible with NGS technology. (Chudova (Guardant) Tr. 1143).
- 1414. [REDACTED] (PX7114 (Stamatiou (StageZero) Dep. at 42) (*in camera*)).
- 1415. Microarray systems are limited in the number of genetic markers they can interrogate. (Chahine (Helio) Tr. 1020).
- 1416. Thermo Fisher's Felton acknowledged that while microarray technology "can generate a large number of data points, their throughput is relatively low compared to the highest throughput gene sequencing platforms." (PX7097 (Felton (Thermo Fisher) Dep. at 41)).
- 1417. [REDACTED]

- [REDACTED]
- (PX7111 (Fesko (Natera) Dep. at 64–65) (*in camera*)).
1418. [REDACTED] (PX7111 (Fesko (Natera) Dep. at 62) (*in camera*)).
1419. Former Ariosa co-founder and CEO Dr. Ken Song testified that Ariosa abandoned its plans for developing oncology tests because ctDNA was not detectable on a microarray. (PX7071 (Song (Omniome) IHT at 98–99)).
1420. Dr. Song testified that detecting ctDNA was “beyond the technical possibilities of an array system” because microarrays do not have the level of sensitivity necessary to detect rare events such as ctDNA. (PX7071 (Song (Omniome) IHT at 99)).
1421. Guardant cannot use microarrays for its screening test in development. (Chudova (Guardant) Tr. 1177).
1422. Dr. Chudova analogized at trial that microarray technology is an “analog TV” while NGS is a “digital TV.” (Chudova (Guardant) Tr. 1143).
1423. Guardant cannot use microarrays in place of NGS for its MCED test because microarrays would not provide the kind of precision that is needed for cancer screening applications. (Chudova (Guardant) Tr. 1177).
1424. Guardant Senior VP of Product, Nitin Sood, explained that microarrays are “very difficult” and “will not work because [MCED testing requires] very deep sequencing. . . . And microarrays just wouldn’t have the sensitivity to analyze the small number of tumor DNA molecules present[.]” (PX7090 (Sood (Guardant) Dep. at 93)).
1425. Mr. Sood testified that microarrays cannot look for the thousands of markers required by Guardant’s MCED test “at the sensitivity required for detection.” (PX7090 (Sood (Guardant) Dep. at 94)).
1426. In comparison to microarray platforms, Dr. Chahine testified that “DNA sequencing” is able to “interrogate the entire genome,” which is “in the billions of base[] [pairs].” (Chahine (Helio) Tr. 1020).
1427. Dr. Chahine testified at trial that he “could say almost with certainty there’s zero chance” of “catch[ing] any markers that” can distinguish cancer in the “early R&D phase” if you “limit[ed] yourself to, for example, 600,000 markers” with a microarray system. (Chahine (Helio) Tr. 1021).

1428. Freenome's Mr. Otte testified that [REDACTED]  
[REDACTED]

[REDACTED]

(PX7055 (Otte (Freenome) IHT at 59) *in camera*)).

1429. Freenome's Mr. Otte testified that [REDACTED]

[REDACTED]

(PX7055 (Otte (Freenome) IHT at 58-61) *in camera*)).

1430. FMI's Perettie testified that microarray technology [REDACTED]  
[REDACTED] (PX7074 (Perettie (FMI-Roche) Dep. at 159) *in camera*)).

1431. [REDACTED]  
[REDACTED] (PX7114 (Stamatiou (StageZero) Dep. at 34-35, 38) *in camera*)).

1432. [REDACTED]  
[REDACTED] (PX7114 (Stamatiou (StageZero) Dep. at 33-34) *in camera*)).

1433. [REDACTED]  
[REDACTED] (PX7114 (Stamatiou (StageZero) Dep. at 34-35) *in camera*)).

1434. [REDACTED]  
[REDACTED] (PX7114 (Stamatiou (StageZero) Dep. at 35) *in camera*)).

1435. [REDACTED] } (PX7114 (Stamatiou (StageZero) Dep. at 50–51) (*in camera*)).
1436. [REDACTED] } (PX7114 (Stamatiou (StageZero) Dep. at 33–34) (*in camera*)).
1437. [REDACTED] } (PX7114 (Stamatiou (StageZero) Dep. at 47–50) (*in camera*)).
1438. [REDACTED] } (PX8540 [REDACTED] (*in camera*)).
1439. [REDACTED] (PX7114 (Stamatiou (StageZero) Dep. at 33–34) (*in camera*); (Rabinowitz (Natera) Tr. 346 (*in camera*)).
1440. Thermo Fisher’s Felton explained that [REDACTED] (PX7070 (Felton (Thermo Fisher) IHT at 68) (*in camera*)).

**2. PCR-Based Technology**

1441. Dr. Felton of Thermo Fisher explained, “A PCR is a polymerase chain reaction. It’s the process of making copies of a template DNA using the enzyme Taq polymerase. You take one copy of DNA, double strand DNA. You separate the two strands. You anneal a small sequence of the Taq polymerase and then rebuild the second strand. So you can generate multiple copies and consider it photocopying DNA and generate as many copies in principle as you wish from that original template.” (PX7070 (Felton (Thermo Fisher) IHT at 66-67)).
1442. [REDACTED] (PX7097 (Felton (Thermo Fisher) Dep. at 37-40); PX7058 (Conroy (Exact) IHT at 122) (*in camera*); PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR) (Although qPCR may be more cost effective than NGS for assays testing for less than 20 targets, qPCR “can only interrogate a limited set of variants” and has “low scalability”)).

1443. PCR technology has several challenges. PCR “can only interrogate a limited set of variants,” has “virtually no discovery power,” and has “low scalability.” (PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR); see PX7040 (Getty (Guardant) IHT at 39-40) (testifying that PCR, in comparison to NGS, does not provide the scale, depth, sensitivity, or turnaround times for blood-based tests)).
1444. PCR is limited to interrogating specific regions or points in the genome to identify the presence or absence of pre-determined target sequences, and PCR is unable to detect novel genetic variants or mutations. (PX7072 (deSouza (Illumina) IHT at 240) (“A PCR test is a type of genomic test where you’re looking at very specific regions of the genome.”); PX7097 (Felton (Thermo Fisher) Dep. at 39)).
1445. The key different between NGS and qPCR is “discovery power.” qPCR “can only detect known sequences. In contrast, NGS is a hypothesis-free approach that does not require prior knowledge of sequencing information. NGS provides higher discovery power to detect novel genes and higher sensitivity to quantify rare variants and transcripts.” (PX0120 at 001 (Illumina, Advantages of next-generation sequencing vs. qPCR) (“discovery power is the ability to identify novel variants.”)).
1446. Andrew Felton, Vice President of Product Development at Thermo Fisher, a leading PCR-based technology provider, acknowledged that PCR-based technology is “entirely unlikely to be scalable or have enough data points generated in a reasonable amount of time [for MCED testing], and therefore, the economics and the scalability of the answer is likely highly unsuited for that environment.” (PX7070 (Felton (Thermo Fisher) IHT at 67)).
1447. PCR is not a substitute for NGS because PCR technology “only allows you to interrogate a very small number of genomic regions at a time,” unlike NGS. (Felton (Thermo Fisher) Tr. at 1994).
1448. [REDACTED] } See (PX7042 (Gao (Singlera) IHT at 38-40); PX7058 (Conroy (Exact) IHT at 65-68) (*in camera*)).
1449. Mr. Felton explained that PCR technologies are “[n]ot able to generate sufficiently large number of data points at scale to make the test economic.” (PX7097 (Felton (Thermo Fisher) Dep. at 38)).
1450. The throughput of PCR is significantly less than NGS. (Felton (Thermo Fisher) Tr. at 1994-1995; PX7097 (Felton (Thermo Fisher) Dep. at 38-39)).
1451. NGS is a better option than PCR for applications in “oncology, inherited disease testing, reproductive health testing. . . .” (Felton (Thermo Fisher) Tr. at 1995).
1452. Andrew Felton, Vice President of Product Development at Thermo Fisher, a leading PCR-based technology provider, acknowledged that PCR-based technology is “entirely unlikely to be scalable or have enough data points generated in a reasonable amount of time [for MCED testing], and therefore, the economics and the scalability of the answer is likely highly unsuited for that environment.” (PX7070 (Felton (Thermo Fisher) IHT at 67)).

1453. Mr. Felton testified that PCR technologies are generally not used to detect unknown DNA variants because PCR “requires the design of a primer, and therefore, a known sequence a priori to understand which variants you’re detecting.” (PX7097 (Felton (Thermo Fisher) Dep. at 39)).

1454. “Generally at this time, [digital PCR is] not considered to be very useful” for multi-cancer early detection testing. (PX7097 (Felton (Thermo Fisher) Dep. at 40)).

1455. Mr. Felton testified that it would “almost certainly” cost more to run MCED tests on PCR, and likely “orders of magnitude” more. (PX7070 (Felton (Thermo Fisher) IHT at 67)).

1456. [REDACTED] (Felton (Thermo Fisher) Tr. at 2010-2011) (*in camera*)).

1457. [REDACTED] }  
[REDACTED] }  
(PX7055 (Otte (Freenome) IHT at 58-61) (*in camera*)).

1458. [REDACTED]  
[REDACTED]



(PX7055 (Otte (Freenome) IHT at 57-58 (*in camera*))).

- 1459. Dr. Gao testified at trial that PCR technology is not suitable for use in the PanSeer test. (Gao (Singlera) Tr. 2893-94).
- 1460. At trial, Dr. Gao explained that “[o]bviously you cannot use PCR to do, you know, 500 readings . . . in a cost-effective way.” (Gao (Singlera) Tr. 2893).
- 1461. Singlera’s Dr. Gao testified that Singlera’s cancer screening test requires a sequencing instrument capable of analyzing “millions of base pairs” of DNA. (PX7042 (Gao (Singlera) IHT at 38-40)).
- 1462. Dr. Gao explained that, “[i]t’s impossible” for Singlera to run its cancer screening test on sequencing instruments that use PCR technology because “PCR technology will only be able to analyze . . . tens of base pair[s].” (PX7042 (Gao (Singlera) IHT at 38-40)).
- 1463. Dr. Gao explained why the fact that PCR can only analyze a small number of base pairs is insufficient for cancer screening:

The analogy I usually use is for police looking at a suspect. If you said the suspect has black hair, then it’s not easy to identify. Then [if] you have a sketch of the suspect with many description[s] . . . the nose, the ear, the eye, the mouth, and [] the height, weight . . . shoe size, so the more kind[s] of biomarker[s], the better description, better sensitivity and the specificity you can detect cancer, especially in many different kind[s] of cancer. . . . That’s why we had to go to thousands of region and millions of base pairs to analyze them.”

(PX7042 (Gao (Singlera) IHT at 39-40)).

- 1464. Dr. Gao testified that there is “no way” that a PCR version of PanSeer could compete with GRAIL’s Galleri test. (PX7042 (Gao (Singlera) IHT at 92)).
- 1465. In contrast to PanSeer, Dr. Gao explained that Singlera’s single-cancer colorectal cancer test, ColonES, is able to use PCR technology—albeit with worse performance: “Because it’s only one cancer type, we can only do a few marker. Basically, we can use qPCR. And it will not have the same high sensitivity, specificity . . .” (PX7042 (Gao (Singlera) IHT at 90-91)).

1466. [REDACTED]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 120-122) (*in camera*)).

1467. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 122) (*in camera*)).

1468. { [REDACTED]

[REDACTED]  
}

(PX7051 (Lengauer (Third Rock Ventures) IHT at 119-20) (*in camera*)).

1469. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 121-22) (*in camera*)).

1470. [REDACTED] (PX7058 (Conroy (Exact) IHT at 65-68) (*in camera*)).

1471. Exact's Conroy testified that { [REDACTED] (PX7058 (Conroy (Exact) IHT at 122) (*in camera*)).

1472. Mr. Conroy testified that by using NGS sequencing technology: { [REDACTED] (PX7058 (Conroy (Exact) IHT at 122) (*in camera*)).

1473. [REDACTED] } (PX7111 (Fesko (Natera) Dep. at 60) (*in camera*)).

1474. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 22) (*in camera*)).

1475. [REDACTED] (Chahine (Helio) Tr. 1068 (*in camera*)).

1476. [REDACTED]  
[REDACTED] (Chahine (Helio) Tr. 1068-69 (*in camera*)).

1477. [REDACTED]  
[REDACTED] (Chahine (Helio) Tr. 1068 (*in camera*); see PX7077 (Chahine (Helio) Dep. at 24) (*in camera*)).

1478. [REDACTED]  
[REDACTED] (PX7077 (Chahine (Helio) Dep. at 24) (*in camera*)).

1479. [REDACTED]  
[REDACTED] } (PX7077 (Chahine (Helio) Dep. at 25) (*in camera*)).

1480. [REDACTED]  
[REDACTED] (Chahine (Helio) Tr. 1068-69 (*in camera*)).  
[REDACTED] (Chahine (Helio) Tr. 1068-69 (*in camera*)).

1481. [REDACTED]  
[REDACTED] (PX7077 (Chahine (Helio) Dep. at 36-37) (*in camera*)).

1482. Guardant’s Mr. Getty explained that PCR technology would not be adequate for cancer screening tests because “you wouldn’t be able to get the scale nor would you be able to mine the depths to find that, you know, proverbial needle in a haystack.” (PX7040 (Getty (Guardant) IHT at 39)).

1483. Mr. Getty testified that PCR technology “couldn’t achieve the sensitivity” required for cancer screening tests. (PX7040 (Getty (Guardant) IHT at 39-40)).

1484. Mr. Getty testified that PCR technology does not have “the ability to read the genome across . . . multiple sequences and really mine the depths of the DNA.” (PX7040 (Getty (Guardant) IHT at 39)).

1485. Guardant’s Mr. Getty testified that PCR technology is unlikely to produce the large number of data points required for MCED and similar tests within a reasonable turnaround time:

The ability to leverage PCR in just -- just by virtue of time that you would need to have in order to do the volume that we’re doing in terms of testing, assuming you could actually achieve the sensitivity, which is really the bigger challenge there, you would be looking at probably doubling or tripling of turnaround times associated with the test going back to the clinician.

(PX7040 (Getty (Guardant) IHT at 39-40)).

1486. Guardant’s Nitin Sood testified that attempting to run its cancer screening test using PCR technology “just wouldn’t work[,]” explaining that, “[b]ecause the number of changes we want to look for [in DNA] and the granularity with which those changes we want to look at, I mean, the fine grain granularity, the single base by resolution that you want to look at, it would not be possible to do that by PCR.” (PX7090 (Sood (Guardant) Dep. at 89-90)).

1487. Guardant’s Sood explained that Guardant cannot run its cancer screening test on PCR technology because, “when you’re looking for multiple regions of a genome with high throughput, with sample multiplexing to bring costs down, I think next-generation sequencing is the platform of choice.” (PX7090 (Sood (Guardant), Dep. at 89-90)).

1488. Guardant cannot use qPCR for its MCED test because it could not design an MCED assay capable of finding rare tumor fragments by only profiling the presence or absence of a small number of particular mutations. (Chudova (Guardant) Tr. 1176-77) (explaining that Guardant’s “technology step relies heavily on profiling a significant portion of the human genome with a sequencing-based readout. So [Guardant] will not be compatible with any QPCR solution.”)).

1489. Quantitative PCR (“qPCR”) technology is suitable for assessing the presence or absence of a small number of mutations whose locations are known up front. (Chudova (Guardant) Tr. 1176; PX0096 at 001 (Illumina, Liquid Biopsy and NGS: Driving translational clinical research to the next level) (“qPCR is efficient when analyzing a small number of variants. However, qPCR assays are limited to the relatively few targets that are specified and assess only specified variant types, thus offering little discovery value.”)).

1490. FMI’s Ms. Perettie testified that PCR technology would not be an option for FMI’s early cancer detection test because [REDACTED] (PX7074 (Perettie (FMI-Roche) Dep. at 159) (*in camera*)).

1491. [REDACTED] } (PX7068 (Perettie (FMI-Roche), IHT at 65) (*in camera*)).

1492. Illumina’s marketing materials also highlight the drawbacks of PCR-based detection technology relative to NGS, noting that “[w]hile qPCR is effective for low target numbers, the workflow can be cumbersome for multiple targets. NGS is preferable for studies with



1496. Proteomics analyzes protein levels as a biomarker for cancer. (PX7100 (Chudova (Guardant) Dep. at 106)).
1497. No existing technology can look at the number of proteins in the body that would be necessary to screen for multiple cancers. (See PX7090 (Sood (Guardant) Dep. at 92-93)).
1498. Using proteomics in place of NGS would require developing a new platform capable of doing so. (See PX7090 (Sood (Guardant) Dep. at 92-93)).
1499. [REDACTED] (PX7100 (Chudova (Guardant) Dep. at 106-107) (*in camera*)).
1500. [REDACTED] } (See, e.g., Cance (American Cancer Society) Tr. 613; Nolan (Freenome) Tr. 2759 (*in camera*)).

**G. SUFFICIENT AND TIMELY ENTRY OF A NEW SHORT-READ NGS PLATFORM SUITABLE FOR MCED TEST DEVELOPERS IS UNLIKELY**

**1. Significant Scientific, Legal, and Commercial Barriers to Entry Exist**

**a) Multiple Companies Have Attempted to Develop an NGS Platform Comparable to Illumina’s and Have Failed**

1501. Roche has spent nearly a decade and millions of dollars attempting to develop an NGS platform and still has not succeeded. (See *infra* Complaint Counsel’s Proposed Findings of Facts ¶¶ 1622-1654).
1502. Qiagen developed and launched an NGS platform but Illumina sued Qiagen for patent infringement and won an injunction that prevented Qiagen from selling its NGS product in the United States, resulting in Qiagen’s exit from the NGS market. (See PX9067 at 017 (Complaint for Violation of Federal Antitrust and California Unfair Competition Laws, *Complete Genomics, Inc., et al. v. Illumina, Inc.*, No. 3:21-cv-00217 (N.D. Cal.) (Jan. 11, 2021)) (“After introducing a sequencing system in 2016, [Qiagen] was forced to abandon the U.S. and worldwide sequencing market because of a series of challenges that Illumina initiated.”) (citing *Illumina, Inc. v. Qiagen, N.V.*, 207 F. Supp. 3d 1081, 1083 (N.D. Cal. 2016) (granting preliminary injunction))).
1503. [REDACTED] (See PX7061 (Davy (Illumina) IHT at 127) (*in camera*)).
1504. [REDACTED] (Rabinowitz (Natera) Tr. 336-37 (*in camera*)).


1505. [REDACTED] (Rabinowitz (Natera) Tr. 336-37 (*in camera*)).
1506. [REDACTED] (Rabinowitz (Natera) Tr. 336-37 (*in camera*)).
1507. [REDACTED] (Rabinowitz (Natera) Tr. 349 (*in camera*)).
1508. Thermo Fisher has spent years and millions of dollars trying to develop an NGS sequencer that performs as well as Illumina’s NGS sequencers and has not yet succeeded (*See supra* Section V.E.1. (Thermo Fisher Is Not an Option for MCED Test Developers); *see also infra* Complaint Counsel’s Proposed Findings of Facts ¶¶ 1577-1585).
1509. Omniome has spent years and millions of dollars trying to develop an NGS sequencer and has yet to complete development let alone commercially launch a sequencer. (*See infra* Complaint Counsel’s Proposed Findings of Facts ¶¶ 1586-1621).
1510. [REDACTED] (Rabinowitz (Natera) Tr. 348 (*in camera*)).
1511. [REDACTED] (PX7070 (Felton (Thermo Fisher) IHT at 38) (*in camera*)).
1512. Thermo Fisher’s Dr. Felton estimates that for company with no prior genome sequencing experience, entry into the NGS market would take “three to five years” and “hundreds of millions of dollars” depending on the complexity of the technology stating that a new company would have to “provide enough differentiation [to] ... gain significant market share” and “building a new technology from scratch is more difficult and expensive than iterating an existing technology.” (PX7070 (Felton (Thermo Fisher) IHT at 39)).
1513. [REDACTED] (Velarde (Singular Genomics) Tr. 4553 (*in camera*)).
1514. [REDACTED] (Velarde (Singular Genomics) Tr. 4554 (*in camera*)).
1515. “[I]n the past decade, there was really no NGS compan[y] that could compete with Illumina in a meaningful, material way.” (PX7124 (He (Element) Dep. at 123)).
1516. An investor question posed to Illumina’s board of directors was to “describe [Illumina’s] competitive position.” Illumina’s response to this question was “[w]e have maintained our market share leadership position despite competitive announcements as evidenced by a

stable win-rate. Customer feedback has been that the Sequel instrument by Pacific Biosciences is complimentary and that the recent [Thermo Fisher] Ion Torrent (Ion S5 and Ion S5 XL) are more revisions of the current platforms than a meaningful advancement.” (PX2551 (Illumina) at 12 (Illumina, Board of Directors Meeting Key Investor Q&A, Jan. 25, 2016)).

b) Illumina Has an Extensive Patent Portfolio That Prevents Entry

- 1517. Dr. Aravanis prepared a response to anticipated investor questions for a large group investor meeting on Monday, February 22, 2021 representing that “Illumina owns a spectrum of IP covering various improvements that enable Illumina’s superior sequencing accuracy, speed, and efficiency. These patents and pending applications have expiration dates ranging from 2023 to beyond 2030. Our patented innovations touch every aspect of the sequencing workflow, including nucleotides, enzymes, reagent mixes, instruments, optics, analysis software, and bioinformatics, which result from Illumina’s significant investments in research and development.” (deSouza (Illumina) Tr. 2229-32; PX2822 (Illumina) at 006-007 (Illumina, Baird Non-Deal Roadshow with Alex Aravanis, Feb. 22, 2021)).
- 1518. Illumina represented to investors in early January 2021, that it has “an extensive intellectual property portfolio” including “exclusive licenses to 901 issued U.S. patents and 650 pending U.S. patent applications .... [Illumina’s] issued and pending patents cover various aspects of our arrays, assays, oligo synthesis, sequencing technology, instruments, digital microfluidics, software, bioinformatics, and chemical-detection technologies, and have terms that expire between 2021 and 2041. [Illumina] continue[s] to file new patent applications to protect the full range of our technologies.” (PX0061 at 009 (Illumina 10K, Jan. 3, 2021)).
- 1519. Singular Genomics describes the NGS sequencer market as characterized by “extensive intellectual property disputes and litigation.” (PX0068 at 013 (Singular Genomics S-1, May 2021)).
- 1520. Singular Genomics describes the NGS sequencing market as an “area in which there are numerous issued patents and patent applications and in which there has been substantial litigation regarding patent and other intellectual property rights.” (PX0068 at 046 (Singular Genomics S-1, May 2021)).
- 1521. [REDACTED] (Velarde (Singular Genomics) Tr. 4548 (*in camera*)).
- 1522. [REDACTED] (See PX7050 (Nolan (Freenome) IHT at 101-03 (*in camera*))).
- 1523. [REDACTED] (PX7071 (Song (Omniome) IHT at 40) (*in camera*)).



1524. Mr. Song of Omniome testified that Illumina has “amassed a fairly large IP estate” surrounding NGS platforms and that Illumina “will use it almost as a weapon ... to try and ensure that they maintain their dominance in the sequencing space.” (PX7071 (Song (Omniome) IHT at 40)).
1525. Natera represented to investors in its Form 10-K that “in the event that it is in our commercial or financial interest or we are forced to transition sequencing platforms ... we may be unable to do so in a commercially sustainable way and that could survive claims of infringement of intellectual property rights of Illumina and other competitors in a timely manner or at all.” (PX0155 at 32 (Natera, 2020 Form 10-K, Dec. 31, 2020)).
1526.  } (Rabinowitz (Natera) Tr. 337 (*in camera*)).

**2. Even if a Company Develops a New NGS Platform, Significant Barriers to Commercialization Exist and It Will Take Years for a New Entrant to Gain the Reputation and Enough Widespread Commercial Use to Be an Option for MCEDs**

a) Illumina Has Widespread Adoption and Good Reputation for Reliability

1527. Dr. Chahine testified at trial that Illumina is the preferred NGS platform because “from a business standpoint [ ] it is just considered the top technology with respect to its ability to sequence [ ] accurately . . . at larger scales” that create “some [very useful] economies of scale.” (Chahine (Helio) Tr. 1044).
1528. Dr. Chahine testified at trial that the Illumina platform is “by far [ ] the preferred one that’s used even at third-party shops” and the “leading one for many different [ ] reasons.” (Chahine (Helio) Tr. 1044).
1529. Dr. Chahine testified Helio is “very familiar with Illumina. That’s what most people trust. That’s what most people have equipment, even third parties.” (PX7077 (Chahine (Helio) Dep. at 26)).
1530. Mr. Gao testified that “unless you show superiority over Illumina, why [would] we want to throw away what we have done to go with you, so we never go with any other company.” (PX7042 (Gao (Singlera) IHT at 60)).
1531. When Singlera chose to use Illumina, it chose the winner: “We had to be solid.” (PX7042 (Gao (Singlera) IHT at 63)).
1532. Dr. Vogelstein testified that Illumina’s NGS sequencers are “incredibly reliable” and elaborated that they “work time and time again, over and over, both in our lab and numerous other labs.” (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 59)).

1533. With respect to Illumina’s NGS sequencers, Dr. Vogelstein testified that Illumina’s “service is superb” and elaborated that his lab does “studies in which [they] have to return results to patients every week and [they’re] on constant alert and anxiety to make sure the instruments don’t break down because patients’ lives depend on them” so they “need absolutely reliable instruments.” (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 59-60)).

1534. Dr. Vogelstein testified that the “know-how that has been obtained on” Illumina’s NGS sequencers “since their beginning is unbelievably strong” and he would characterize as “priceless.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 59)).

1535. [REDACTED] } (PX7105 (Getty (Guardant) Dep. at 239-40) (*in camera*)).

1536. Dr. Lengauer explained:

[REDACTED]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 109-10) (*in camera*)).

b) MCED Customers Would Not Switch to a New Platform Until It Has Widespread Adoption and Demonstrated Reliability

1537. [REDACTED] (PX7107 (deSouza (Illumina) Dep. at 259 (*in camera*) (referring to PX2544 (Illumina)-025)).

1538. In a conference call with investors, Illumina CEO Mr. deSouza noted the U.S. NGS market poses “significant hurdles” for entry and that Illumina “continue[s] to push this at a higher and higher bar in the market”:

[T]he U.S. is a very sophisticated genomics market both in terms of the research market and the clinical market. And so customers here have high expectations around the quality of the products, the accuracy of the product, the reliability of the product, the ease of the workflow, the validation of the products by the rest of the market. And so these present significant hurdles for anyone else coming

in that we do believe that we continue to push this at a higher and higher bar in the market.

(PX2544 (Illumina) at 025 (Email from T. Peterson, JP Morgan, to F. deSouza, Sept. 5, 2019, attaching JP Morgan Life Sciences CEO Conference Call Transcript, Sept. 3, 2019)).

1539. A February 2020 UBS/DeciBio presentation on NGS use generally stated that “[d]espite increasing competition, Illumina is poised to maintain its leadership position over the next 5+ years” and notes that “NGS users have created an ‘Illumina ecosystem’ (e.g., bioinformatics pipeline) making it hard for competing technologies.” (PX2030 (Illumina) at 006 (UBS/DeciBio, NGS and Spatial Omics Landscape and Trends, Feb. 24, 2020)).
1540. The same UBS/DeciBio presentation states that ““Many players are expected to enter the market in the coming years but are unlikely to materially affect the market in the near term due to R&D timelines and Illumina ecosystem incompatibility.” (PX2030 (Illumina) at 010 (UBS/DeciBio, NGS and Spatial Omics Landscape and Trends, Feb. 24, 2020)).
1541. The same UBS/DeciBio presentation projects that “Illumina will continue to dominate the space,” with other sequencing firms “carving out niches.” (PX2030 (Illumina) at 009 (UBS/DeciBio, NGS and Spatial Omics Landscape and Trends, Feb. 24, 2020) (referring specifically to Thermo Fisher’s “ex-U.S. commercial reach” and BGI’s “(ex-U.S.) leadership position”).
1542. Illumina CEO Mr. deSouza distinguished U.S. clinical customers as being particular focused on “high accuracy results”: “[O]n the clinical side, it’s especially important that products deliver high accuracy results.” (PX2544 (Illumina) at 025 (Email from T. Peterson, JP Morgan, to F. deSouza, Sept. 5, 2019, attaching JP Morgan Life Sciences CEO Conference Call Transcript, Sept. 3, 2019)).
1543. When Illumina launches a new platform, clinical customers do not immediately switch, but rather wait a year or two to observe the platform’s performance. (deSouza (Illumina) Tr. 2409-10).
1544. Once customers have observed how a new sequencer “performs in the real market,” customers will bring in a single sequencer to validate their workflows and train people on the new sequencer. (deSouza (Illumina) Tr. 2410).
1545. The validation process for evaluating a new sequencer takes months or quarters. (deSouza (Illumina) Tr. 2410).
1546. Only after observing the sequencer’s performance in the market and validating the customer’s workflow on the new sequencer will a customer begin selling its tests on a new sequencer. (deSouza (Illumina) Tr. 2409-10).
1547. It is “not uncommon” for clinical customers to wait years to adopt a new sequencer—“it could be three-plus years after a new sequencer comes out.” (deSouza (Illumina) Tr. 2410).

1548. Clinical customers take years to adopt a new sequencer, because they wait to see how it will perform in the real world, then perform validation. (deSouza (Illumina) Tr. 2450).
1549. Clinical customers will ramp up on a new sequencer 2.5 to 3 years after the sequencer's launch. (deSouza (Illumina) Tr. 2450).
1550. Mr. deSouza pointed to customer adoption of the NovaSeq to exemplify how clinical customers' adoption cycles can take years: "For example, NovaSeq was launched on -- in 2017, first half of 2017, and we still have a substantial portion of our NovaSeq customers that are new to high throughput or new to Illumina, and they are only now bringing the NovaSeq into their environment." (deSouza (Illumina) Tr. 2410-11).
1551. In evaluating a new NGS Platform, Dr. Lengauer testified that [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 105) (*in camera*)).
1552. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 105) (*in camera*)).
1553. [REDACTED] (PX7045 (Chudova (Guardant) IHT at 115-16) (*in camera*)).
1554. [REDACTED] (Chudova (Guardant) Tr. 1228-29) (*in camera*)).
1555. [REDACTED] (PX7055 (Otte (Freenome) IHT at 74) (*in camera*)).

c) Gaining Widespread Adoption Among Customers is Time Consuming and Difficult Because of Contracting Practices and Reputational Barriers

1556. Singular represented to investors that "customers' willingness and ability to adopt new products and workflows, including in light of commercial pressures applied by our competitors and pre-existing long-term contracts with our competitors" is a commercial risk that could prevent customer adoption of a new NGS Sequencing platform. (PX0068 at 031-32 (Singular Genomics S-1, May 2021)).

1557. [REDACTED]  
[REDACTED] (Velarde (Singular Genomics) Tr. 4550 (*in camera*)).
1558. Dr. He testified that Element Biosciences is “worried ... that Illumina can use its market power ... and perhaps lock down their customers with multi-year agreements ... to prevent any new NGS provider[] from entering the space or just make that very, very difficult.” (PX7124 (He (Element) Dep. at 122)).
1559. [REDACTED]  
[REDACTED] } (PX7071 (Song (Omniome) IHT at 58-59) (*in camera*)).
1560. Singular represented to investors that “[i]f our products fail to achieve early customer and scientific acceptance, we may not be able to achieve broader market acceptance for our products and our revenue and prospects may be harmed.” (PX0068 at 025 (Singular Genomics S-1, May 2021)).
1561. Singular represented to investors that “the life sciences community is comprised of a small number of early adopters and key opinion leaders (KOLs) who significantly influence the rest of the community and the market-place in general.” (PX0068 at 026 (Singular Genomics S-1, May 2021)).
1562. Singular represented to investors that “[e]nsuring that early adopters and KOLs publish research involving the use of our products is critical to ensuring our products gain widespread acceptance and market growth.” (PX0068 at 026 (Singular Genomics S-1, May 2021)).
1563. Singular represented to investors that “[i]f early adopters and KOLs do not favorably describe the use of our products, do not compare our products favorably to existing product and technologies, or negatively describe the use and operation of our products in publications, it may drive potential customers away from our products and prevent broader market acceptance of our products, which could harm our business, financial condition and results of operations. (PX0068 at 026 (Singular Genomics S-1, May 2021)).
1564. [REDACTED]  
[REDACTED] (PX7070 (Felton (Thermo Fisher) IHT at 28) (*in camera*)).
1565. Mr. Conroy explained his expectation that once a company signs a supply agreement with Illumina, [REDACTED] } (PX7058 (Conroy (Exact) IHT at 150-151) (*in camera*)).
1566. Natera represented to investors in its Form 10-K that although it is “not bound to use exclusively Illumina’s sequencing instruments and reagents for conducting our sequencing, ... if we use other sequencing and reagents for more than specified percentages of our total

NIPT clinical volume, we may no longer be entitled to discounts from Illumina.” (PX0155 at 15 (Natera 2020 Form 10-K, Dec. 31, 2020).

d)

[REDACTED]

1567.

[REDACTED]

1568.

[REDACTED]

1569.

[REDACTED]

1570.

[REDACTED]

1571.

[REDACTED]

1572.

[REDACTED]

e) MCED Customers Would Be Reluctant to Use NGS Platform with Unclear Freedom to Operate from Illumina’s Patents

1573. Dr. Gao testified that Singlera has “invested tens of millions, hundreds of millions [of] dollars into product development” and it will “only work with [a] company with clear IP rights.” (Gao (Singlera) Tr. 2895).

1574.

[REDACTED]

1575. Multiple MCED customers are reluctant to work with BGI because of the uncertainty of BGI's freedom to operate in the U.S. without infringing Illumina's patents. (*See supra* Section V.E.2.c).

**3. No NGS Platform Likely to Enter the NGS Market That Would Be a Viable Option for MCED Test Developers in a Timely Manner**

1576. [REDACTED] } (PX7050 (Nolan (Freenome) IHT at 101-104) (*in camera*)).

a) Thermo Fisher

1577. [REDACTED] } (Felton (Thermo Fisher) Tr. 2011) (*in camera*)).

1578. [REDACTED] (Felton (Thermo Fisher) Tr. at 2012) (*in camera*)).

1579. [REDACTED] } (Felton (Thermo Fisher) Tr. 2012-2013) (*in camera*)).

1580. [REDACTED] } (PX7070 (Felton (Thermo Fisher) IHT at 55) (*in camera*)).

1581. Respondents' own expert, Dr. Richard Cote, acknowledged that Thermo Fisher's sequencing platform is "somewhere between the mid and low throughput" Illumina sequencing platforms. (Cote Tr. 3760).

1582. [REDACTED] } (Felton (Thermo Fisher) Tr. 2013) (*in camera*)).

1583. [REDACTED] } (PX7070 (Felton (Thermo Fisher) IHT at 56) (*in camera*)).

1584. Thermo Fisher’s Dr. Felton acknowledged that despite its research and development work, [REDACTED] (PX7070 (Felton (Thermo Fisher) IHT at 59-60) (*in camera*); see also PX7070 (Felton (Thermo Fisher) IHT at 60-61) (testifying that NGS platforms offered by Thermo Fisher, Pacific Biosciences and Oxford Nanopore “are really not suited to [MCED] testing.”)).

1585. [REDACTED] } (Felton (Thermo Fisher) Tr. 2015) (*in camera*)).

b) Omniome

1586. Omniome was founded in 2013. (PX7071 (Song (Omniome) IHT at 13)).

1587. Omniome currently does not have a commercial NGS platform on the market. (deSouza (Illumina) Tr. 2473-74).

1588. [REDACTED] (PX7071 (Song (Omniome), IHT at 38-39) (*in camera*)).

(1) [REDACTED]

1589. [REDACTED] } (PX7096 (Song (Omniome) Dep. at 13–16) (*in camera*)).

1590. [REDACTED] } (PX7096 (Song (Omniome) Dep. at 17–18) (*in camera*)).

1591. [REDACTED] } (PX7096 (Song (Omniome) Dep. at 18–19) (*in camera*)).

1592. [REDACTED] (PX7096 (Song (Omniome) Dep. at 20-27) (*in camera*)).

1593. [REDACTED] (PX7071 (Song (Omniome) IHT at 27–28) (*in camera*)).



1594. [REDACTED] } (PX7096 (Song (Omniome) Dep at 28) (in camera)).

1595. [REDACTED] (PX7096 (Song (Omniome) Dep at 28–29) (in camera)).

1596. [REDACTED] (PX7096 (Song (Omniome) Dep. at 13–29)) (in camera)).

1597. [REDACTED] } (PX7071 (Song (Omniome) IHT at 22-25) (in camera)).

(2) [REDACTED]

1598. [REDACTED] (PX7096 (Song (Omniome) Dep. at 144-45) (in camera)).

1599. Omniome has had to make changes to the design of its sequencer “quite a bit” since it began development. (PX7096 (Song (Omniome) Dep. at 143) (in camera)).

1600. [REDACTED] } (PX7096 (Song (Omniome) Dep. at 143) (in camera)).

1601. [REDACTED] } (PX7096 (Song (Omniome) Dep. at 144) (in camera)).

1602. [REDACTED] (PX7096 (Song (Omniome) Dep. at 144–45) (in camera)).

1603. [REDACTED] } (PX7096 (Song (Omniome) Dep. at 144–45) (in camera)).

1604. [REDACTED] } (PX7096 (Song (Omniome) Dep. at 145) (in camera)).

1605. [REDACTED] } (PX7096 (Song (Omniome) Dep. at 145) (in camera)).

1606. The role of early access customers is to provide manufacturers with feedback on a multitude of different factors. (PX7096 (Song (Omniome) Dep. at 145–46)).

1607. Dr. Song testified that depending on the feedback that early access customers provide, companies think about whether they want to delay the commercial launch to incorporate the feedback into the instrument. (PX7096 (Song (Omniome) Dep. at 146)).

1608. Mr. Song warned that, [REDACTED] (PX7071 (Song (Omniome) IHT at 28) (*in camera*)).

1609. [REDACTED] (PX7071 (Song (Omniome) IHT at 27-28) (*in camera*)).

1610. [REDACTED] } (PX7071 (Song (Omniome) IHT at 24-25) (*in camera*)).

1611. Omniome anticipates spending another \$60 to \$80 million before having an NGS platform ready for early access. (PX7071 (Song (Omniome) IHT at 26)).

1612. Depending on the feedback from early access release, [REDACTED] } (PX7071 (Song (Omniome) IHT at 26-27) (*in camera*)).

(3) [REDACTED] }

1613. [REDACTED] } (PX7071 (Song (Omniome) IHT at 15) (*in camera*)).

1614. [REDACTED] (PX7071 (Song (Omniome) IHT at 22) (*in camera*)).

1615. [REDACTED] } (PX7055 (Otte (Freenome) IHT at 121-22) (*in camera*)).

1616. [REDACTED] } (PX7121 (Otte (Freenome) Dep. at 63) (*in camera*)).

1617. [REDACTED]

- [REDACTED] (PX7121 (Otte (Freenome) Dep. at 63-64) (*in camera*)).
1618. [REDACTED] } (PX7121 (Otte (Freenome) Dep. at 64) (*in camera*)).
1619. [REDACTED] (PX7055 (Otte (Freenome) IHT at 121-22) (*in camera*)).
1620. Freenome’s current CEO testified that Freenome determined that “[Omniome (and others) isn’t] far enough along and that [it’s] ability to meet [Freenome’s] requirements, even just the high-level must-have requirements wasn’t sufficient[.]” (Nolan (Freenome) Tr. 2741).
1621. [REDACTED] } (PX7071 (Song (Omniome) IHT at 41-42) (*in camera*)).
- c) [REDACTED]
1622. [REDACTED]
1623. [REDACTED]
1624. [REDACTED]
1625. [REDACTED]
1626. [REDACTED]
1627. [REDACTED]
1628. [REDACTED]

1629. [REDACTED]

1630. [REDACTED]

1631. [REDACTED]

1632. [REDACTED]

1633. [REDACTED]

1634. [REDACTED]

1635. [REDACTED]

1636. [REDACTED]

1637. [REDACTED]

1638. [REDACTED]

1639. [REDACTED]

1640. [REDACTED]

1641. [REDACTED]

1642. [REDACTED]

1643. [REDACTED]

1644. [REDACTED]

1645. [REDACTED]

1646. [REDACTED]

[REDACTED]

[REDACTED]

1647. [REDACTED]

- [REDACTED] } (Chudova (Guardant) Tr. 1225) (*in camera*).
1648. [REDACTED] (PX7045 (Chudova (Guardant) IHT at 114) (*in camera*)).
1649. [REDACTED] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).
1650. [REDACTED] } (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).
1651. [REDACTED] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).
1652. [REDACTED] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).
1653. [REDACTED] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).
1654. [REDACTED] (PX2776 (Illumina) at 001 (Email from J. Seaton, Illumina, to F. deSouza, Illumina, Feb. 13, 2018) (*in camera*)).

d) Singular Genomics

1655. Singular is developing an NGS sequencer called the G4 sequencer. (Velarde (Singular Genomics) Tr. 4513).
1656. Singular's target throughput for its sequencer is [REDACTED] } (PX7117 (Velarde (Singular Genomics) Dep. at 48-49) (*in camera*)).

1657. [REDACTED]  
 [REDACTED]  
 (See PX7117 (Velarde (Singular Genomics) Dep. at 48-49 (*in camera*)); see also PX0085 at 001 (Illumina NovaSeq 6000 System Specifications); see also (PX2169 (Illumina) at 025 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).
1658. [REDACTED]  
 [REDACTED] (Velarde (Singular Genomics) Tr. 4549-50 (*in camera*)).
1659. [REDACTED] }  
 (Velarde (Singular Genomics) Tr. 4545 (*in camera*)).
1660. [REDACTED] } (Velarde (Singular Genomics) Tr. 4545 (*in camera*)).
1661. Singular identified as a risk to its investors that “we may not be able to generate sufficient revenue to achieve and maintain profitability.” (PX0068 at 023 (Singular Genomics S-1, May 2021)).
1662. [REDACTED] }  
 (Velarde (Singular Genomics) Tr. 4552 (*in camera*)).
1663. [REDACTED]  
 [REDACTED] } (Velarde (Singular Genomics) Tr. 4552 (*in camera*)).
1664. [REDACTED] } (Velarde (Singular Genomics) Tr. 4555 (*in camera*)).
1665. Singular identified as a risk to its investors that “our limited operating history makes it difficult to evaluate our future prospects.” (PX0068 at 023 (Singular Genomics S-1, May 2021)).
1666. Singular identified as a risk to its investors that “we may require substantial additional funding.” (PX0068 at 035 (Singular Genomics S-1, May 2021)).
1667. Singular identified as a risk to its investors that if it is unable to obtain additional funding, it may be required “to delay, scale back, or cease our product development or commercialization activities.” (PX0068 at 035 (Singular Genomics S-1, May 2021)).
1668. Singular represented to investors that “[i]f we are sued for infringing, misappropriating or otherwise violating intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.” (PX0068 at 045 (Singular Genomics S-1, May 2021)).
1669. Singular represented to investors that it “expect[s] to be exposed to, or threatened with, future litigation by third parties, including our primary competitors, who have patent and

other intellectual property rights and may allege that our research and development activities, products, manufacturing methods, software and/or technologies infringe, misappropriate or otherwise violate their intellectual property rights.” (PX0068 at 046 (Singular Genomics S-1, May 2021)).

1670. Singular represented to investors that it “expect[s] that [it’s] competitors will, in connection with our launch of our G4 Integrated Solution and our planned PX Integrated Solution and later stage product offerings assert that we are infringing, or have in the past infringed, as part of our research and development activities, their patent and other intellectual property rights and that we are employing their proprietary technology without authorization.” (PX0068 at 046 (Singular Genomics S-1, May 2021)).

1671. Singular represented to investors that as a result of another company initiating a patent lawsuit against Singular upon launch of its NGS sequencer, “[w]e could also be required to obtain a license to such patents in order to continue the development and commercialization of the infringing product or technology” which “may require substantial payments or cross-licenses” and “have a material adverse effect on our business, financial condition, results of operation or prospects.” (PX0068 at 046 (Singular Genomics S-1, May 2021)).

1672. [REDACTED] }  
(Velarde (Singular Genomics) Tr. 4548 (*in camera*)).

1673. [REDACTED]  
(Velarde (Singular Genomics) Tr. 4549 (*in camera*)).

1674. [REDACTED] } (Velarde (Singular Genomics)  
Tr. 4548 (*in camera*)).

1675. [REDACTED]  
} (Velarde (Singular Genomics) Tr. 4548-49 (*in camera*)).

1676. [REDACTED] } (Velarde (Singular  
Genomics) Tr. 4549 (*in camera*)).

1677. [REDACTED] } (PX7058 (Conroy (Exact)  
IHT at 127) (*in camera*)).

1678. [REDACTED] }  
(Conroy (Exact) Tr. 1754 (*in camera*)).



1679. [REDACTED]  
[REDACTED] (PX7058 (Conroy (Exact) IHT at 127 *in camera*)).

1680. [REDACTED]  
[REDACTED] (PX7058 (Conroy (Exact) IHT at 127-28 *in camera*)).

1681. [REDACTED]  
[REDACTED] } (PX7058 (Conroy (Exact) IHT at 129) *in camera*)).

1682. [REDACTED]  
[REDACTED] } (Conroy (Exact) Tr. 1760 *in camera*)).

1683. Mr. Michael Nolan of Freenome testified that [REDACTED]  
[REDACTED] (PX7094 (Nolan (Freenome) Dep. at 168-69) *in camera*)).

e) [REDACTED]

1684. [REDACTED]  
[REDACTED]

1685. [REDACTED]  
[REDACTED]

1686. [REDACTED]  
[REDACTED]

1687. [REDACTED]  
[REDACTED]

1688. [REDACTED]  
[REDACTED]

- 1689. [REDACTED]
- 1690. [REDACTED]
- 1691. [REDACTED]
- 1692. [REDACTED]
- 1693. [REDACTED]
- 1694. [REDACTED]
- 1695. [REDACTED] } (PX6082 (Grail Responses & Objections to FTC Requests for Admissions) at 7 (RFA No. 3) (*in camera*)).
- 1696. [REDACTED]
- 1697. [REDACTED]
- 1698. [REDACTED] } (Chudova (Guardant) Tr. 1225 (*in camera*))).
- 1699. [REDACTED] (Chudova (Guardant) Tr. 1226-27 (*in camera*)).

f)

[REDACTED]

1700. [REDACTED]

1701. [REDACTED]

1702. [REDACTED]

1703. [REDACTED]

1704. [REDACTED]

1705. [REDACTED]

1706. [REDACTED]

1707. [REDACTED]

1708. [REDACTED]

1709. [REDACTED]

1710. [REDACTED]

1711. [REDACTED]

1712. [REDACTED]

1713. [REDACTED]

1714. [REDACTED]

1715. [REDACTED]

1716. [REDACTED]

1717. [REDACTED]

1718. [REDACTED]

1719. [REDACTED] } (Chudova (Guardant) Tr. 1226-27) (*in camera*).

1720. [REDACTED] } (PX7055 (Otte (Freenome) IHT at 121-22) (*in camera*)).

1721. [REDACTED] (PX7055 (Otte (Freenome) IHT at 121-22) (*in camera*)).

1722. [REDACTED]

[REDACTED] } (PX7121 (Otte (Freenome) Dep. at 65) *(in camera)*).

1723. [REDACTED]

g) No Other NGS Platforms in Development Is Likely to Replace Illumina

1724. Dr. Vogelstein testified that although “[t]here may be other companies that are developing sequencing platforms . . . [,] the only effective platform today is Illumina’s platform.” (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 67-68)).

1725. [REDACTED] } (Conroy (Exact) Tr. 1582 *(in camera)*).

1726. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 117-18) *(in camera)*).

1727. Mr. Nolan testified that “with the information I have today, I don’t know of a suitable substitute [for Illumina’s NGS platform] anywhere on the near or midterm horizon.” (Nolan (Freenome) Tr. 2729).

1728. Guardant’s Mr. Getty testified at trial that Guardant cannot run its MCED test on non-Illumina NGS platforms like those from companies currently developing NGS sequencing platforms. (Getty (Guardant) Tr. 2688).

1729. Mr. Nolan testified that switching to an alternative to Illumina’s NGS platform, “within three years . . . would be highly unlikely, and I’m not sure if it’s even, you know -- when it would be possible after that.” (Nolan (Freenome) Tr. 2729-30).

1730. [REDACTED] (PX7055 (Otte (Freenome) IHT at 74) *(in camera)*).

1731. [REDACTED] (Rabinowitz (Natera) Tr. 341 *(in camera)*).

**4. Even if Another NGS Platform Entered the U.S. Market Comparable to Illumina’s Current Platform, Illumina Plans to Continue to Improve its Existing Platform**

1732. [REDACTED] } (Aravanis (Illumina) Tr. 1794 (*in camera*); deSouza (Illumina) Tr. 2270-2271 (*in camera*); PX2169 (Illumina) at 024 (Illumina Strategic Plan 2021-2025, Oct. 23, 2020) (*in camera*); PX5026 (Illumina) at 009 (FY20-25 Strategic Plan Initial Revenue Discussion, Jun. 4, 2020) (*in camera*)).

1733. [REDACTED] (RX1254 (Illumina) at 009 [REDACTED] (*in camera*)).

1734. [REDACTED] } (Aravanis (Illumina) Tr. 1797; PX6056 (Illumina) at 017 (Illumina, Narrative Response of Illumina, Inc. to the Second Request, Mar. 1, 2021) (*in camera*)) ( [REDACTED] ); RX1254 (Illumina) at 010 [REDACTED] (*in camera*) ( [REDACTED] ); PX2558 (Illumina) at 005 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*) [REDACTED] ); PX2169 (Illumina) at 025 (Illumina Strategic Plan 2021 - 2025, Oct. 23, 2020) (*in camera*) ( [REDACTED] [REDACTED] ))).

1735. [REDACTED] (Aravanis (Illumina) Tr. 1799 (*in camera*); PX2612 (Illumina) at 013 [REDACTED] (*in camera*)).

1736. [REDACTED] (deSouza (Illumina) Tr. 2301 (*in camera*)).

1737. [REDACTED] (PX2558 (Illumina) at 005-006 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*); PX2560 (Illumina) at 007 [REDACTED] (*in camera*)). [REDACTED] (Aravanis (Illumina) Tr. 1800) (*in camera*)).

1738. [REDACTED] (Aravanis (Illumina) Tr. 1788, 1797-1798) (*in camera*)).

1739. Illumina’s NovaSeq 6000 platform is currently its most powerful commercially available NGS instrument. A NovaSeq running two S4 flow cells at once can generate 20 billion

reads in one 44-hour run. (Aravanis (Illumina) Tr. 1788; PX2595 (Illumina) at 005 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*)).

1740. [REDACTED] (PX2595 (Illumina) at 005 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*)).

1741. [REDACTED] (Aravanis (Illumina) Tr. 1799 (*in camera*); PX2169 (Illumina) at 025, 028 (Illumina Strategic Plan 2021-2025, Oct. 23, 2020) (*in camera*); [REDACTED] })).

1742. [REDACTED] (RX1254 (Illumina) at 014 (*in camera*)). [REDACTED] } (RX1254 (Illumina) at 014 (*in camera*)).

1743. [REDACTED] (RX1254 (Illumina) at 017 [REDACTED])

1744. [REDACTED] } (Aravanis (Illumina) Tr. 1799-1800) (*in camera*); PX6056 (Illumina) at 017 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*); RX1254 (Illumina) at 018 [REDACTED] (*in camera*); PX5026 (Illumina) at 009 (FY20-25 Strategic Plan Initial Revenue Discussion, Jun. 4, 2020 ([REDACTED] ) (*in camera*)); PX2581 (Illumina) at 001, 003 [REDACTED] (*in camera*); PX7072 (deSouza (Illumina) IHT at 247) (*in camera*)).

1745. [REDACTED] (PX2560 (Illumina) at 004-005 [REDACTED] (*in camera*); PX2558 (Illumina) at 006, 008 (Board of Directors Executive Session, Feb. 9, 2021) (*in camera*); see PX7107 (deSouza (Illumina) Dep. at 271) (*in camera*)).

1746. [REDACTED] } (RX1994 (Illumina) at 023, 025 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)). [REDACTED]

[REDACTED] } (RX1994 (Illumina) at 025 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)).

1747. [REDACTED] } (Aravanis (Illumina) Tr. 1801).

1748. [REDACTED] (PX7107 (deSouza (Illumina) Dep. at 277-78) (*in camera*)).

1749. [REDACTED] (RX1254 (Illumina) at 013 [REDACTED] (*in camera*)).

1750. [REDACTED] (RX1254 (Illumina) at 013 (*in camera*)). [REDACTED] (RX1254 (Illumina) at 013 [REDACTED] (*in camera*)). [REDACTED] (RX1254 (Illumina) at 013 [REDACTED]).

1751. [REDACTED] } (RX1254 (Illumina) at 028 [REDACTED] (*in camera*)). [REDACTED] } (RX1254 (Illumina) at 028 [REDACTED] (*in camera*)). [REDACTED] (RX1254 (Illumina) at 029 [REDACTED] (*in camera*)).

1752. [REDACTED] } (RX1254 (Illumina) at 009 [REDACTED] (*in camera*)). [REDACTED] } (RX1254 (Illumina) at 011 [REDACTED] (*in camera*)).

1753. [REDACTED] (RX1254 (Illumina) at 009 [REDACTED] (*in camera*)).

1754. [REDACTED] } (PX7123 (Fellis (Illumina) Dep. at 29) (*in camera*)).



1755. [REDACTED] } (deSouza (Illumina) Tr. 2273-2274 (*in camera*); PX2334 (Illumina) at 003 (Email from A. Aravanis, Illumina, to F. deSouza, Illumina, attaching “Factory Sequencing Roadmap,” Nov. 4, 2020) (*in camera*)).

1756. [REDACTED] (deSouza (Illumina) Tr. 2273 (*in camera*); PX2334 (Illumina) at 003 (Email from A. Aravanis, Illumina, to F. deSouza, Illumina, attaching “Factory Sequencing Roadmap,” Nov. 4, 2020) (*in camera*)).

1757. [REDACTED] } (deSouza (Illumina) Tr. 2273-74 (*in camera*)).

1758. [REDACTED] (deSouza (Illumina) Tr. 2277-2278 (*in camera*)).

1759. [REDACTED] } (deSouza (Illumina) Tr. 2269-2270 (*in camera*)).

1760. [REDACTED] (deSouza (Illumina) Tr. 2277-2278 (*in camera*)).

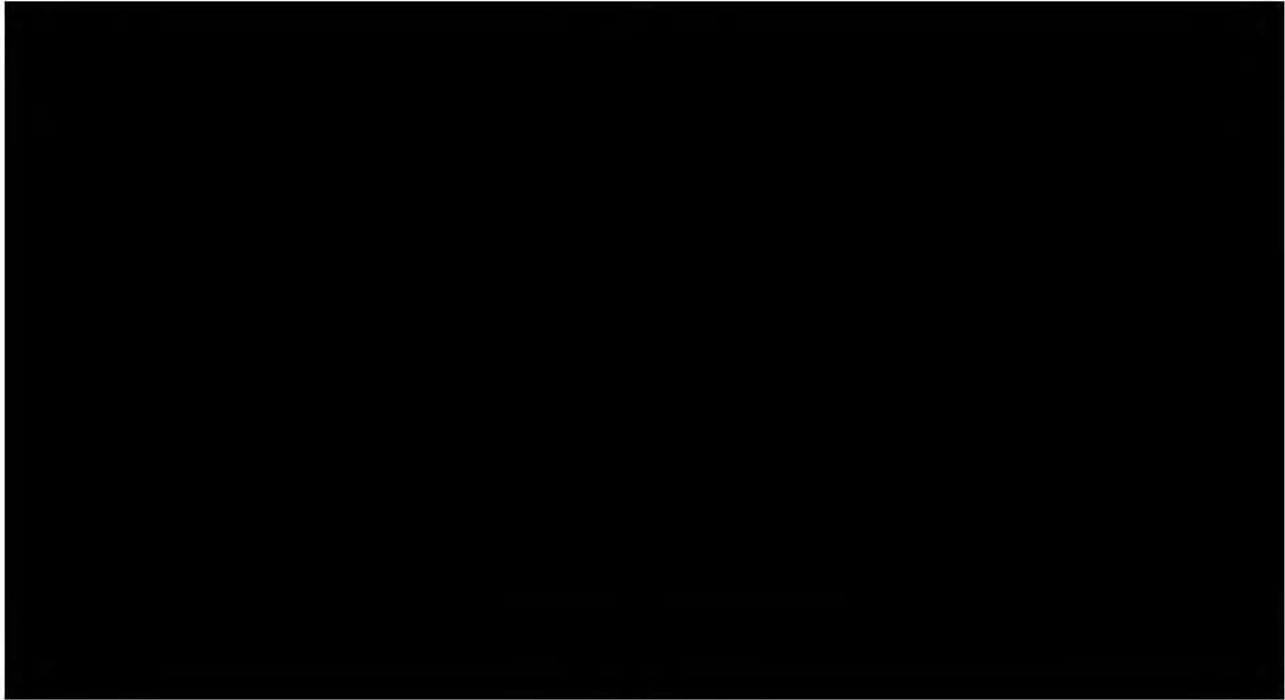
1761. [REDACTED] } (deSouza (Illumina) Tr. 2277-2279 (*in camera*); PX2853 (Illumina) at 001, 004 (Email from E. Milsovic, Illumina, to F. deSouza, Illumina, attaching “Executive Session,” May 2, 2021) (*in camera*)).

1762. [REDACTED] (deSouza (Illumina) Tr. 2277-2279; PX2853 (Illumina) at 001, 004 (Email from E. Milsovic, Illumina, to F. deSouza, Illumina, attaching “Executive Session,” May 2, 2021) (*in camera*)).

1763. [REDACTED] (deSouza (Illumina) Tr. 2277-2279 (*in camera*); PX2853 (Illumina) at 004 (Email from E. Milsovic, Illumina, to F. deSouza, Illumina, attaching “Executive Session,” May 2, 2021) (*in camera*)).

1764. According to Illumina's Strategic Plan, { [REDACTED] } (RX1994 (Illumina) at 025 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*) (see inset image).

{



}

1765. [REDACTED] } (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)). [REDACTED]

[REDACTED] (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)).

1766. [REDACTED] (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)).

1767. [REDACTED] } (RX1994 (Illumina) at 037 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching "Illumina Strategic Plan 2021 - 2025," Nov. 5, 2020) (*in camera*)).

H. SWITCHING TO ANOTHER NGS PLATFORM WOULD CAUSE SIGNIFICANT DELAYS, REQUIRE SIGNIFICANT COSTS, AND POSE REGULATORY AND FINANCIAL RISKS FOR MCED TEST DEVELOPERS

1. MCED Tests are Developed to Run on a Specific NGS Platform

1768. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 179 (*in camera*)).

1769. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 179 (*in camera*)).

1770. Thrive's Lengauer testified, [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 71-72 (*in camera*); see also PX7051 (Lengauer (Third Rock Ventures) IHT at 70) (*in camera*)).

1771. [REDACTED] {A [REDACTED] (PX7110 (Conroy (Exact) Dep. at 66-67) (*in camera*)).

1772. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 124) (*in camera*)).

1773. Exact's CEO, Kevin Conroy, testified, [REDACTED] } (PX7058 (Conroy (Exact) IHT at 128-129) (*in camera*)).
1774. [REDACTED] } (Chudova (Guardant) Tr. 1301-1302 (*in camera*)).
1775. [REDACTED] } (PX7045 (Chudova (Guardant) IHT at 40-41) (*in camera*)).
1776. According to Nitin Sood, Guardant's Senior VP of Product, "Illumina is central to what we do. . . . [W]e built part of our world around the Illumina ecosystem." (PX7090 (Sood (Guardant) Dep. at 112-13)).
1777. [REDACTED] } (Rabinowitz (Natera) Tr. 415 (*in camera*)).
1778. [REDACTED] (Chahine (Helio) Tr. 1071 (*in camera*)).
1779. [REDACTED] (PX6049 (Grail) at 023 (Grail, Narrative Response to FTC Second Request, Mar. 1, 2021) (*in camera*)).
2. [REDACTED]
- a) Grail
1780. [REDACTED] } (Freidin (Grail) Tr. 3066 (*in camera*)).
1781. [REDACTED] } (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).
1782. [REDACTED] } (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).

b) [REDACTED]

1783. [REDACTED]

1784. [REDACTED]

1785. [REDACTED]

1786. [REDACTED]

1787. [REDACTED]

1788. [REDACTED]

[REDACTED]

[REDACTED]

1789. [REDACTED]

1790. [REDACTED]

1791. [REDACTED]

[REDACTED]

[REDACTED]

1792. [REDACTED]

1793. [REDACTED]

1794. [REDACTED]

c) [REDACTED]

1795. [REDACTED]

1796. [REDACTED]

1797. [REDACTED]

1798. [REDACTED]

d) Guardant

1799. [REDACTED] } (PX7045 (Chudova (Guardant) IHT at 109-10) (*in camera*)).

1800. [REDACTED] (Chudova (Guardant) Tr. 1235-36; see also PX7045 (Chudova (Guardant) IHT at 105-13 ([REDACTED] } (*in camera*)).

1801. [REDACTED] } (Chudova (Guardant) Tr. 1234-35) (*in camera*)).

1802. [REDACTED] } (Chudova (Guardant) Tr. 1234-35) (*in camera*)).

1803. [REDACTED] (Chudova (Guardant) Tr. 1307-08 (*in camera*)).

1804. [REDACTED] (Chudova (Guardant) Tr. 1308-09) (*in camera*)).

1805. [REDACTED]

[REDACTED]

(PX7045 (Chudova (Guardant) IHT at 49-51) *in camera*)).

1806. [REDACTED] (Chudova (Guardant) Tr. 1234-35 *in camera*)).

1807. [REDACTED] (Chudova (Guardant) Tr. 1234-35 *in camera*)).

1808. [REDACTED] } (Chudova (Guardant) Tr. 1235-36) *in camera*)).

1809. [REDACTED] (Chudova (Guardant) Tr. 1236) *in camera*)).

1810. After redesigning its MCED test, a test developer would need to revalidate its test on the new platform and, at a minimum, perform “a smaller scale clinical sample analysis.” (PX7100 (Chudova (Guardant) Dep. at 82)).

1811. To switch to a new platform, an MCED test developer must redesign its test to be compatible with the new NGS instrument, which although “theoretically possible” involves a “significant amount of development work.” (PX7045 (Chudova (Guardant) IHT at 53-56)).

1812. Guardant’s Chudova explained, [REDACTED] (PX7045 (Chudova (Guardant) IHT at 88) *in camera*)).

1813. [REDACTED] } (PX7045 (Chudova (Guardant) IHT at 109-10) *in camera*)).

1814. [REDACTED]



[REDACTED]

(PX7045 (Chudova (Guardant) IHT at 109-10) (*in camera*)).

1815. Dr. Chudova testified that after Guardant receives FDA approval for its screening test “[t]he cost of switching [to a new platform] would increase” because “if we have approval on existing sequencing configuration today and then we go back into development to adapt our library preparation workflows to be compatible with different sequencing system and then adapt the software to the new system, we have to go through the same validation cycle again given the amount of modifications in the workflow, so we’ll have to conduct full analytical validation of the system given that scope of change.” (PX7045 (Chudova (Guardant) IHT at 111-12)).
1816. Guardant’s Dr. Chudova testified that the costs of switching could be so significant that it may no longer make business sense to pursue the test because switching would “delay and potentially annihilate existence of such test on the market because the cost of development and implementation would start being prohibitive from a business standpoint to continue on that path, so again I think it would lead from the path to 2023 launch to infinite path to launch.” (PX7045 (Chudova (Guardant) IHT at 118-19)).
1817. Dr. Chudova testified that the only circumstance in which Guardant would consider switching from Illumina to Roche is “in a very hypothetical space, if Illumina cuts all of the supply to their reagents and instruments and there’s nobody else on the market that becomes—and they have something that works, which they don’t today, we could discuss that option. I don’t think it’s a serious discussion for us today given the three above are not met.” (PX7045 (Chudova (Guardant) IHT 114)).
1818. Guardant represented to investors in its 2019 Form 10-K filed with the Securities and Exchange Commission that:

The use of equipment or materials furnished by [any] replacement suppliers would require us to alter our laboratory operations. Transitioning to a new supplier would be time-consuming and expensive, may result in interruptions in our laboratory operations, could affect the performance specification of our laboratory operations or could require that we revalidate our tests. There can be no assurance that we will be able to secure alternative equipment, reagents and other materials, bring such equipment, reagents and materials on line, and revalidate our tests without experiencing disruptions in workflow. In the case of alternative supplier for Illumina, for example, there can be no assurance that replacement sequencers and various associated reagents will be available or will meet our quality control and performance requirements for our laboratory operations.

(PX0059 at 045 (Guardant 2019 Form 10-K)).

e) [REDACTED]

1819. [REDACTED]

1820. [REDACTED]

1821. [REDACTED]

1822. [REDACTED]

1823. [REDACTED]

1824. [REDACTED]

f) Singlera

1825. Even if a hypothetical NGS platform had similar characteristics to Illumina, MCED test developers would not necessarily use the new platform due to high switching costs. (See PX7042 (Gao (Singlera) IHT at 55-56)).

1826. Singlera’s Dr. Gao testified that switching would mean “redevelopment . . . . You [have] to redo it every – replicate it every study you done on Illumina . . . to convince yourself this is comparable.” (PX7042 (Gao (Singlera) IHT at 55-56)).

1827. Dr. Gao testified that Singlera would have to conduct a new viability trial if Singlera switched to a non-Illumina NGS platform. (PX7042 (Gao (Singlera) IHT at 56-57)).

- 1828. Singlera would not be able to use data from its trials using Illumina’s instrument in a new viability trial if Singlera switched to a non-Illumina sequencer. (PX7042 (Gao (Singlera) IHT at 57)).
- 1829. Switching to a new NGS platform would mean that “many years [have] gone down the drain and there’s hundreds of million[s] of dollar[s] down the drain” which would be bad for business and for investors. (PX7042 (Gao (Singlera) IHT at 58)).
- 1830. Dr. Gao testified that if Singlera switched from Illumina’s NGS platform to Thermo Fisher’s NGS platform, for example, “you just need to spend more money, more time to develop, and why we want bother [sic] with that.” (PX7042 (Gao (Singlera) IHT at 48-49)).
- 1831. Singlera’s Gao testified that switching to a non-Illumina NGS platform would delay the commercial launch of Singlera’s cancer screening test “at least a year or two . . . or it could be five, seven years longer, because we had to make sure every study we did with Illumina, which works or won’t work. Then we had to publish again on a journal to show [that the non-Illumina platform] work[s]. That will be a long process.” (PX7042 (Gao (Singlera) IHT at 56)).

g) [REDACTED]

1832. [REDACTED]

1833. [REDACTED]

1834. [REDACTED]

h) [REDACTED]

1835. [REDACTED]

1836. [REDACTED]

1837. [REDACTED]

1838. [REDACTED]

1839. [REDACTED]

[REDACTED]

**3. Illumina, Grail, and Other NGS Market Participants Recognize High Switching Costs**

a) Despite the Risks From Having a Sole Supplier, Grail Is Not Likely to Switch NGS Platforms

1840. If Grail were to switch to a non-Illumina sequencer, Grail CEO Hans Bishop testified that it's "a reasonable assumption" that Grail would need to revalidate its test on the non-Illumina sequencer. (Bishop (Grail) Tr. 1339).

1841. Grail identified the risks associated with switching its MCED test to a new NGS system. (Bishop (Grail) Tr. 1339-41).

1842. [REDACTED] (Freidin (Grail) Tr. 3133 (*in camera*)).

1843. [REDACTED] } (Freidin (Grail) Tr. 3066 (*in camera*)).

1844. Grail's Freidin testified that [REDACTED]

- [REDACTED] } (PX7066 (Freidin (Grail) IHT at 183) (*in camera*)).
1845. [REDACTED] } (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).
1846. [REDACTED] (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).
1847. [REDACTED] (PX7066 (Freidin (Grail) IHT at 212-13) (*in camera*)).
1848. [REDACTED] } (PX7103 (Jamshidi (Grail) Dep. at 169) (*in camera*)).
1849. Grail has never physically performed technical evaluations of non-Illumina sequencers. (PX7103 (Jamshidi (Grail) Dep. at 33)).
1850. Dr. Jamshidi testified that, to his knowledge, Grail has never conducted any feasibility analyses of running Galleri on alternative platforms. (PX7103 (Jamshidi (Grail) Dep. at 171)).
1851. Dr. Jamshidi explained that if Grail replaced Illumina’s NGS platform with a NGS platform from another provider, Grail “would have to probably do some additional work just to make sure, for example, that the key metrics are in line with the new instruments that you are bringing in.” (PX7103 (Jamshidi (Grail) Dep. at 181-82)).
1852. Grail’s Jamshidi testified, “even if you, you know, just bring in a new instrument of a similar brand and characteristics, you would actually do some qualification on that instrument where you would test it and just make sure it works properly and has the right characterizations.” (PX7103 (Jamshidi (Grail) Dep. at 182)).
1853. Grail’s Form S-1 identified several risks to Grail from switching suppliers, including its NGS supply from Illumina, as follows:
- Transitioning to a new supplier for this equipment or these materials would be time-consuming and expensive, could result in interruptions in or otherwise affect the performance specifications of our laboratory operations and sample processing or could require that we revalidate our products and, if we receive FDA clearance or approval for our products, could require a new submission to FDA and other regulatory bodies to approve or clear such changes.
- (PX4082 (Grail) at 034 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

- 1854. At trial, Mr. Bishop confirmed the risk of switching suppliers as stated in the Form S-1, stating: “our understanding of the risks are as written in the sentence you’ve highlighted for us. Transitioning to a new supplier for the equipment or materials listed above could take time, could be expensive, could result in interruptions and, as it goes on to say, could require that we revalidate our products if we receive FDA clearance or approval for those products, so it’s speculating on a number of scenarios.” (Bishop (Grail) Tr. 1341).
- 1855. Grail’s Form S-1 identified a “consistent source of supply” as a risk to Grail that could force Grail to alter its laboratory operations and test procedures: “[W]e purchase certain products on a purchase order basis and cannot guarantee a consistent source of supply. The use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and sample collection and processing and related procedures.” (PX4082 (Grail) at 034 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
- 1856. Grail’s Form S-1 specifies that a qualitative substitute for Illumina “may not be available at all”: “In the case of attempting to obtain an alternative supplier for Illumina, Streck, or Twist, replacement instruments and associated reagents, tubes, and panels that meet our quality control and performance requirements may not be available at all, or may not be available on reasonable terms or in a timely manner.” (PX4082 (Grail) at 034 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).
- 1857. Grail’s Form S-1 explains how delays or difficulty in securing supply or revalidating equipment and reagents could cause “significant delays in commercializing” Grail’s products and alter Grail’s financial condition:

If we encounter delays or difficulties in securing, reconfiguring or revalidating the equipment, reagents and other materials that we require for our laboratory operations and sample collection and processing, we would likely face significant delays in commercializing our products and our business, financial condition, results of operations, and growth prospects would be adversely affected.

(PX4082 (Grail) at 034 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

- 1858. [REDACTED]  
[REDACTED]  
(PX4140 (Grail) at 004 (R&D Portfolio Planning - Part B, Sequencing Technology) (*in camera*)).


b) Illumina Recognizes High Switching Costs

- 1859. [REDACTED]  
[REDACTED] (PX2117  
(Illumina) at 006  
[REDACTED] (*in camera*)).

- 1860. According to Dr. Febbo, Illumina’s Chief Medical Officer, switching an LDT’s NGS platform takes approximately six to twelve months. (Febbo (Illumina) Tr. 4325).
- 1861. Illumina represented to investors in its 2020 Form 10-K that “customers invest time in selecting and learning to use a new product and may be reluctant to switch once that selection is made.” (PX0061 at 013 (Illumina 2020 Form 10-K)).
- 1862. Illumina represented to investors in its 2020 Form 10-K that “customers in our markets display a significant amount of loyalty to their initial supplier of a particular product ....” (PX0061 at 015 (Illumina 2020 Form 10-K)).

c) Other Industry Participants Acknowledge High Switching Costs

1863. Dr. Felton explained, “it’s very difficult once you generated your data sets to show that you can detect that. Typically those data sets require many tens to hundreds of thousands of patient samples to show that you can detect it sensitively and specifically. And you would have to do some level of equivalence testing to show the new technology could recapitulate the data you generated on that original data set, which is not an insubstantial amount of work in and of itself.” (PX7070 (Felton (Thermo Fisher) IHT at 61)).

1864.  } (Felton (Thermo Fisher) Tr. 2009-2010 (*in camera*)).

1865. Dr. Felton explained, “[f]or comparability of data sets. You want to ensure that your data from one technology platform is as comparable as possible. Introducing new technologies can lead to difficulty in interpreting between the two data sets.” (PX7070 (Felton (Thermo Fisher) IHT at 29)).

1866. Dr. Felton testified that customers are reluctant to switch NGS platforms because once “you have generated research data sets on a single platform, it’s generally preferable that you continue to use the same platform for comparability over time, and ... changing technologies becomes more difficult[] unless there are very compelling reasons to do so.” (PX7070 (Felton (Thermo Fisher) IHT at 29)).

1867.   
 }

[REDACTED]

1868.

[REDACTED]

1869.

[REDACTED]

1870.

[REDACTED]

1871.

[REDACTED]

**4. Switching NGS Platforms Is Even More Difficult if the MCED Test Has Begun the FDA Approval Process**

1872.

[REDACTED]  
(PX7058 (Conroy (Exact) IHT at 151-54) (*in camera*)).

1873.

[REDACTED]



[REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 78-80) (*in camera*)).

1874.

[REDACTED] (PX7058 (Conroy (Exact) IHT at 151-52) (*in camera*)).

1875.

[REDACTED] } (PX7058 (Conroy (Exact) IHT at 151-54) (*in camera*)).

1876.

[REDACTED] (PX7058 (Conroy (Exact) IHT at 153-54) (*in camera*)).

1877.

[REDACTED] (PX7058 (Conroy (Exact) IHT at 153) (*in camera*)).

1878.

[REDACTED] (Conroy (Exact) Tr. 1582).

1879.

[REDACTED] (Conroy (Exact) Tr. 1583).

1880.

[REDACTED] } (Conroy (Exact) Tr. 1582).

1881.

[REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 87-88) (*in camera*)).

1882. [REDACTED] } (Chudova (Guardant) Tr. 1286-87 (*in camera*)).

1883. Guardant’s Chudova explained that clinical trials and regulatory approvals are tied to the particular NGS instrument and its associated reagents used to develop an MGED test:

[O]nce you’ve submitted the data to -- and once you’ve locked the system, characterized it through analytical validation and submitted your data from that analytical validation for consideration for an IDE [“Investigational Device Exemption”], you’re locked. You cannot modify reagents. You cannot modify any component of the system without additional validation and approval from the agency to continue conducting the clinical trial with a modified device.

(PX7045 (Chudova (Guardant) IHT at 73-74)).

1884. [REDACTED]

1885. [REDACTED]

1886. [REDACTED]

1887. [REDACTED]

1888. Switching may also require redoing entire clinical trials or obtaining new regulatory approvals, which could take “a couple years to finish, then a couple years to basically submit and get published.” (PX7042 (Gao (Singlera) IHT at 57)).

1889. Singlera could not use the data it has already accumulated using Illumina’s system— “there’s no practical use.” (PX7042 (Gao (Singlera) IHT at 57)).

1890. Freenome’s Nolan testified that [REDACTED]

[REDACTED]

(PX7050 (Nolan (Freenome) IHT at 111) (*in camera*)).

1891. [REDACTED]

[REDACTED]

(PX7050 (Nolan (Freenome) IHT at 112) (*in camera*)).

1892. [REDACTED] (Chahine (Helio) Tr.  
1070-71 (*in camera*)).

1893. [REDACTED]

1894. [REDACTED]

1895. [REDACTED]

1896. [REDACTED]

1897. [REDACTED]

1898. [REDACTED]

1899. [REDACTED]

1900. Thermo Fisher’s Felton testified that in order for an MCED test developer to switch NGS instruments after it received FDA approval on a particular instrument, “you have to generate equivalence data to show that the answers that you generate of the second technology are exactly the same as the first technology. And the FDA may require -- may require a lot of data to generate that evidence.” (PX7070 (Felton (Thermo Fisher) IHT at 64)).

1901. According to Phillip Febbo, Illumina’s Chief Medical Officer, switching a test’s NGS platform when that test has already received a PMA could take nine to 18 months. (Febbo (Illumina) Tr. 4325-26).

**VI. COMPETITORS ARE RACING TO DEVELOP MCED TESTS**

1902. [REDACTED] (PX6049 (Grail) at 034 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

1903. [REDACTED] (PX6049 (Grail) at 034 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

**A. EXACT SCIENCES IS DEVELOPING AN MCED TEST CALLED CANCERSEEK**

**1. Exact Is a Commercial Oncology Company That Launched Cologuard, an FDA-Approved and CMS-Reimbursed Stool-Based Colorectal Cancer Screening Test**

- 1904. Exact is headquartered in Madison, Wisconsin with locations across the United States and in Europe. (PX7058 (Conroy (Exact) IHT at 33-34)).
- 1905. Exact has experience bringing cancer screening tests to market from initial biomarker identification all the way to the patient. (PX7058 (Conroy (Exact) IHT at 24)).
- 1906. Exact has five core values, one of which is innovation. (Conroy (Exact) Tr. 1541).
- 1907. At trial, Mr. Conroy explained what innovation means to Exact:

Innovation means looking at a complex problem and thinking about it in different ways, ways that maybe others have never thought about solving those problems, and then investing in a collaborative effort to solve them, bringing together people of all different perspectives and backgrounds and experiences and skill sets to do so. Cologuard is an example of that. Oncotype DX is an example of that. These were far-out-there ideas when first thought of, and so it is a core value to constantly innovate and work with others internally and externally so that you can make a difference in people's lives.

(Conroy (Exact) Tr. 1541-42).

- 1908. In April 2009, Exact's start-up business was developing a colon cancer screening test and a pan-cancer screening test from a blood draw. (Conroy (Exact) Tr. 1532).
- 1909. Today, Exact develops and sells tests that look at hereditary or germline cancers, that screen for cancer, that indicate the best cancer treatment for a patient's cancer, and a test that detects the recurrence of cancer. (Conroy (Exact) Tr. 1531).
- 1910. [REDACTED] (PX7058 (Conroy (Exact) IHT at 19-20; 54-55) (*in camera*)).
- 1911. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 157; PX7091 (Lengauer (Third Rock Ventures) Dep. at 13-14) (*in camera*); PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29, 29-32) (*in camera*)).
- 1912. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 158; PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*)).
- 1913. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 28) (*in camera*)).

1914. [REDACTED] (PX7058 (Conroy (Exact) IHT at 19-20; 83-84) (*in camera*)).

1915. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 83-84) (*in camera*)).

**2. In January 2021, Exact Acquired Thrive, the Developer of an MCED Test Called CancerSEEK**

1916. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 12) (*in camera*); PX7058 (Conroy (Exact) IHT at 201-02) (*in camera*); Conroy (Exact) Tr. 1550-51)).

1917. Exact completed its acquisition of Thrive in early January 2021. (PX4331 (Grail) (Email Attaching Exact Sciences Completes Acquisition of Thrive Earlier Detection, Creating a Leader in Blood-Based, Multi-Cancer Screening, Jan. 5, 2021); PX7051 (Lengauer (Third Rock Ventures) IHT at 24)).

1918. [REDACTED] (PX7110 (Conroy (Exact) Dep. at 12-13) (*in camera*)).  
[REDACTED] } (PX7110 (Conroy (Exact) Dep. at 12-13) (*in camera*); PX7058 (Conroy (Exact) IHT at 200) (*in camera*)).

1919. Thrive was founded in 2019 by Third Rock Ventures. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 27); Lengauer (Third Rock Ventures) Tr. 155-156).

1920. CancerSEEK was co-developed by Dr. Bert Vogelstein at Johns Hopkins University. (Conroy (Exact) Tr. 1542-43; PX7101 (Vogelstein (Johns Hopkins University), Dep. at 27); *see* Conroy (Exact) Tr. 1542-43 (testifying that Dr. Vogelstein developed CancerSEEK within his own lab)).

1921. Thrive’s predecessor in the development of the CancerSEEK test, PapGene, first described the screening test in Science magazine in approximately 2016 or 2017. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 40, 46)).

1922. Dr. Vogelstein “ran clinical studies to demonstrate the ability from a single blood draw to detect cancer earlier across many different types of cancer.” (Conroy (Exact) Tr. 1542-43).

1923. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 38) (*in camera*)).

1924. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 38) (*in camera*)).
1925. Dr. Vogelstein is the Clayton Professor of Oncology and Co-Director of the Ludwig Center for Cancer, Genetics and Therapeutics at the Sidney Kimmel Comprehensive Cancer Center of Johns Hopkins University School of Medicine. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 63-64)).
1926. Dr. Vogelstein has devoted his career to researching and understanding the role of genetic alterations in human cancer and he, along with his team, has been credited with a number of scientific breakthroughs in this area. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 64); PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 2)).
1927. Dr. Vogelstein holds a joint appointment in molecular biology and genetics at the Johns Hopkins University and as an investigator at the Howard Hughes Medical Institute. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 64)).
1928. Alongside teams of researchers, Dr. Vogelstein helped discover that “a relatively small number of genes [play] a major role in most human cancer types.” (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 2)).
1929. Dr. Vogelstein and the group of researchers with whom he works were awarded the international prize from the American Association of Cancer Research for “pioneering the development of liquid biopsies.” (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 78-79)).
1930. Dr. Vogelstein’s lab is currently working on using “the genetic alterations responsible for cancer to develop new diagnostic tests to identify cancers earlier and new therapies to treat patients with advanced disease.” (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 4)).
1931. Dr. Vogelstein’s lab is currently developing tests that rely on NGS to “find cancer DNA in a small amount of blood or bodily fluids and can be used to detect cancer in asymptomatic individuals, personalize therapies to combat the unique genetic alterations within a tumor, and to monitor cancer’s response to treatment.” (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶¶ 4, 6)).
1932. Dr. Vogelstein testified that his lab “published the first description of cancer genomes, what we called cancer genome landscapes, using an Illumina instrument” in approximately 2009 or 2010. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 61)).
1933. Dr. Vogelstein previously served as a consultant to Thrive—a role that involved advising Thrive on the science and scientific issues associated with improving its test in development. (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 30)).

1934. Dr. Vogelstein testified that his work at Johns Hopkins University and Howard Hughes Medical Institute includes an unpaid collaboration agreement with Thrive intended to facilitate “work[ing] together to develop the best test possible for [Thrive’s] earlier diagnosis of cancer.” (PX7101 (Vogelstein (Johns Hopkins University), Dep. at 36-37)).

**3. CancerSEEK is an MCED Test Designed to Detect All Cancer Types Using Multiple Analytes and Next Generation Sequencing**

1935. Exact, through Thrive, is developing an MCED test called CancerSEEK. (Lengauer (Third Rock Ventures) Tr. 157; PX7091 (Lengauer (Third Rock Ventures) Dep. at 13-14) (*in camera*); PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29, 29-32) (*in camera*)).

1936. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 158; PX7051 (Lengauer (Third Rock Ventures) IHT at 28) (*in camera*)).

1937. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 28-29) (*in camera*)).

1938. CancerSEEK “is a test...intended to detect all types of cancers.” (Lengauer (Third Rock Ventures) Tr. 159-60).

1939. [REDACTED] } (Conroy (Exact) Tr. 1650 (*in camera*)).

1940. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 53-55, 57-59) (*in camera*)).

1941. CancerSEEK uses NGS and protein detection to accurately find cancers with a high level of specificity. (Conroy (Exact) Tr. 1544).

1942. [REDACTED] (PX7051 (Conroy (Exact) IHT at 29-32) (*in camera*)).

1943. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 33-34) (*in camera*)).

1944. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 39) (*in camera*)).



1945. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 175 (*in camera*); Conroy (Exact) Tr. 1544; PX7091 (Lengauer (Third Rock Ventures) Dep. at 13-14) (*in camera*); see PX7051 (Lengauer (Third Rock Ventures) IHT at 28-37) (*in camera*) (testifying that [REDACTED] )).

1946. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 34) (*in camera*)).

1947. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 35-36) (*in camera*)).

1948. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 35-36) (*in camera*)).

1949. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 36) (*in camera*)).

1950. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 36) (*in camera*)).

1951. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 36) (*in camera*)).

1952. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 36-37) (*in camera*)).

1953. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 144) (*in camera*)).

1954. [REDACTED]

- [REDACTED] } (Conroy (Exact) Tr. 1571 (*in camera*)).
1955. [REDACTED] (PX8572 (Exact) at 046 (Exact Sciences, Innovation & Technology Committee Spring Meeting Presentation, Apr. 16, 2021 (*in camera*)) [REDACTED] [REDACTED]; PX7091 (Lengauer (Third Rock Ventures) Dep. at 17-19) (*in camera*)).
1956. Exact's CEO Mr. Conroy confirmed at trial that, for CancerSEEK, Exact is continuing to explore multiple different biomarker combinations. (Conroy (Exact) Tr. 1717).
1957. [REDACTED] [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 39-40, 142) (*in camera*)).
1958. [REDACTED] [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 33-37) (*in camera*)).
1959. [REDACTED] [REDACTED] } (Conroy (Exact) Tr. 1622 (*in camera*)).
1960. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 171; PX6049 (Grail) at 036 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)) [REDACTED] [REDACTED] }).
1961. [REDACTED] [REDACTED] (Conroy (Exact) Tr. 1628-29 (*in camera*)).
1962. [REDACTED] (Conroy (Exact) Tr. 1583 (*in camera*); see PX7051 (Lengauer (Third Rock Ventures) IHT at 69-70) (*in camera*)) ([REDACTED] [REDACTED] })).

a) [REDACTED]

1963. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 270-71 (*in camera*); see Conroy (Exact) Tr. 1655-56 (*in camera*)).

1964. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 270-72 (*in camera*)).

1965. [REDACTED] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 67-68) (*in camera*)).

1966. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 270-72 (*in camera*)).

1967. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 270-72 (*in camera*)).

1968. [REDACTED] (PX7110 (Conroy (Exact) Dep. at 244) (*in camera*)).

b) Exact Plans to Continue Improving CancerSEEK Using NGS to Compete with Other MCED Test Developers

1969. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 139-40) (*in camera*)).

1970. Dr. Lengauer testified that even if performance of CancerSEEK is “outstanding,” Thrive “want[s] to always improve [its] test, and with that spirit in mind, [Thrive has] engaged in further improvements of the test while [ ] preparing towards a registrational trial.” (Lengauer (Third Rock Ventures) Tr. 168-69).

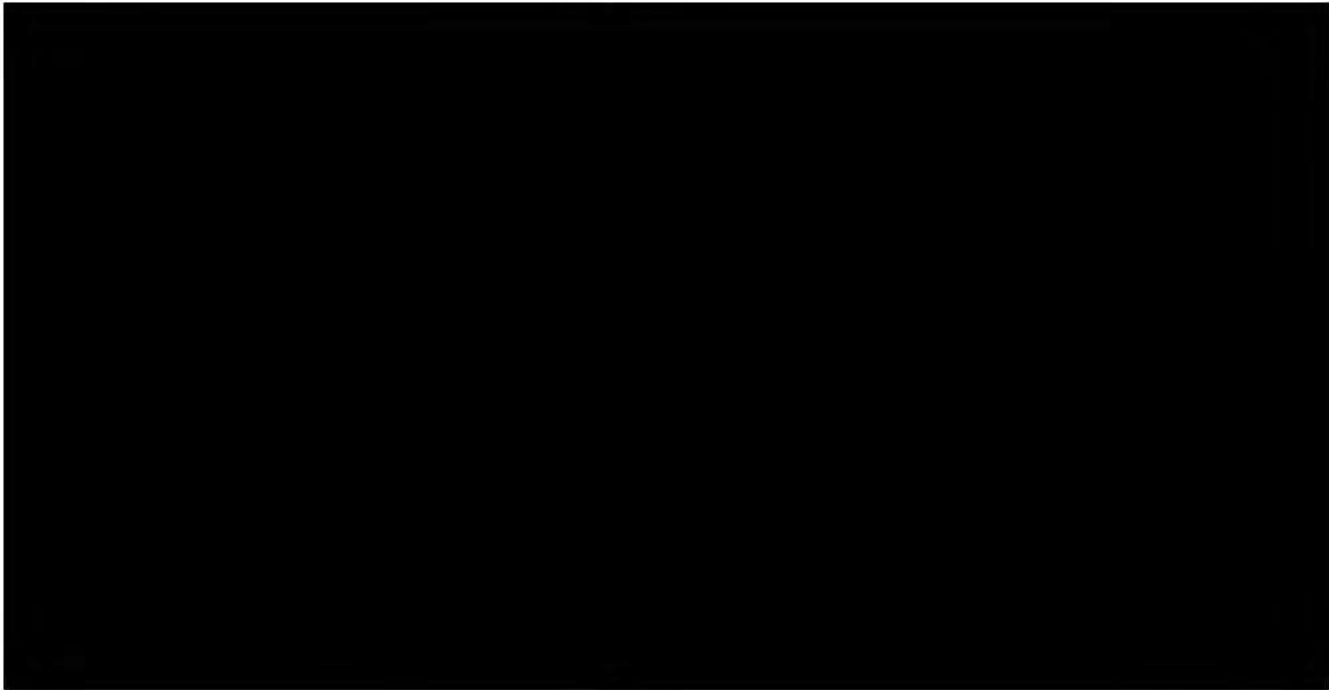
1971. Innovation has allowed Thrive and Exact to constantly improve CancerSEEK “with the use of next-generation sequencing technologies and other technologies.” (Conroy (Exact) Tr. 1546).

1972. Innovation has improved the CancerSEEK product. (Conroy (Exact) Tr. 1546).

1973. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 140 *(in camera)*)).

1974. [REDACTED] (RX0074 (Exact) at 008 *(in camera)* (see inset image)).

}



}

(RX0074 (Exact) at 008 [REDACTED] *(in camera)*)).

1975. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 141 *(in camera)*)).

1976. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 141 *(in camera)*)).

1977. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 141 (*in camera*))).

1978. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 142 (*in camera*))).

1979. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 187 (*in camera*)).

1980. Mr. Conroy testified at trial that Exact plans on continuing to innovate to develop the CancerSEEK product “[e]very day.” (Conroy (Exact) Tr. 1546).

1981. Mr. Conroy stated at trial that Exact “absolutely” plans to continue innovating to develop the CancerSEEK product for the benefit of patients. (Conroy (Exact) Tr. 1546).

1982. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 140 (*in camera*))).

1983. [REDACTED] } (Conroy (Exact) Tr. 1615 (*in camera*)).

1984. [REDACTED] } (Conroy (Exact) Tr. 1615 (*in camera*)).

1985. [REDACTED] } (Conroy (Exact) Tr. 1615 (*in camera*)).

1986. [REDACTED] } (Conroy (Exact) Tr. 1615-16 (*in camera*)).

1987. [REDACTED] } (Conroy (Exact) Tr. 1617 (*in camera*)).

1988. [REDACTED] } (Conroy (Exact) Tr. 1576-77 (*in camera*)).

1989. At trial, Respondents' expert, Dr. Richard Cote, agreed that [REDACTED] } (Cote, Tr. 3823 (*in camera*)).

c) [REDACTED] }

1990. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 146-47; 157 (*in camera*)); PX7058 (Conroy (Exact) IHT at 142 (*in camera*)); PX8402 (Exact/Thrive) at 002 [REDACTED] (*in camera*)).

1991. [REDACTED] } (Conroy (Exact) Tr. 1625 (*in camera*)).

1992. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 142 (*in camera*)); (Conroy (Exact) Tr. 1558 (*in camera*))).

1993. [REDACTED] } (Conroy (Exact) Tr. 1625 (*in camera*)). [REDACTED] } (Conroy (Exact) Tr. 1625 (*in camera*)).

1994. [REDACTED] (Conroy (Exact) Tr. 1558 (*in camera*)).

1995. [REDACTED] } (Conroy (Exact) Tr. 1627-28 (*in camera*)).

1996. [REDACTED] } (Conroy (Exact) Tr. 1558-59 (*in camera*)).

1997. [REDACTED] } (Conroy (Exact) Tr. 1558 (*in camera*)).

1998. [REDACTED] } (Conroy (Exact) Tr. 1558-59 (*in camera*)); PX7058 (Conroy (Exact) IHT at 143 (*in camera*)) ( [REDACTED] })).

1999. [REDACTED] } (Conroy (Exact) Tr. 1556-57 (*in camera*)).

2000. [REDACTED] (Conroy (Exact) Tr. 1626 (*in camera*)). [REDACTED] } (Conroy (Exact) Tr. 1626 (*in camera*)).

2001. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 160-62 (*in camera*))).

2002. [REDACTED] (PX7109 (Daly (Singular Genomics) Dep. at 180 (*in camera*))).

2003. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 145 (*in camera*))).

2004. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 145 (*in camera*))).

2005. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 145 (*in camera*))).

2006. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 145-46 (*in camera*))).

2007. [REDACTED] (PX7058 (Conroy (Exact) IHT at 146 (*in camera*))).

4. [REDACTED]

2008. [REDACTED] (PX7058 (Conroy (Exact) IHT at 141 (*in camera*))).

2009. [REDACTED] (PX7110 (Conroy (Exact) Dep. at 33) (*in camera*)).

2010. A registrational trial is what “devices, tests, and so on [usually seek] or companies usually seek approval by the agency, in this case the FDA, that evaluates the benefit/risk ratio and... can give the approval stamp to a test.” The FDA’s approval stamp is “very, very important for acceptance of tests in the community” and “for potential reimbursement of the test.” (Lengauer (Third Rock Ventures) Tr. 169).

2011. [REDACTED] (PX7051 ((Lengauer (Third Rock Ventures) Tr. 190 (*in camera*); Lengauer (Third Rock Ventures) IHT at 157 (*in camera*); PX8402 (Exact/Thrive) at 002 [REDACTED] (*in camera*))).

2012. [REDACTED] (Conroy (Exact) Tr. 1628 (*in camera*)).

2013. [REDACTED] (PX8402 (Exact/Thrive) at 002 [REDACTED] (*in camera*)).

2014. [REDACTED] (Conroy (Exact) Tr. 1556-57 (*in camera*)).

5. **CancerSEEK Has Already Undergone a Prospective, Interventional Clinical Trial, and Exact is Preparing for Its FDA Registrational Trial**

2015. There are two published studies on CancerSEEK. (Conroy (Exact) Tr. 1697).

a) The Cohen Study

2016. [REDACTED] (Conroy (Exact) Tr. 1545-46; Lengauer (Third Rock Ventures) Tr. 202 (*in camera*)).



2017. The first CancerSEEK study, referred to as the “Cohen study,” was published in the Journal of Science in 2018. (RX3142 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).
2018. The Cohen study examined CancerSEEK’s ability to “detect eight common cancer types through [the] assessment of the levels of circulating proteins and mutations in cell-free DNA.” (RX3142 at 001 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).
2019. The Cohen study applied CancerSEEK to 1,005 patients with “nonmetastatic clinically detected cancers of the ovary, liver, stomach, pancreas, esophagus, colorectum, lung, or breast.” (RX3142 (Cohen et al., Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test)).
2020. The Cohen study focused on eight cancer types: ovary, liver, stomach, pancreas, esophagus, colorectal, lung, and breast. (RX3142 (Cohen et al., Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test)).
2021. Mr. Conroy explained at trial that the Cohen study did not use the current version of CancerSEEK. (Conroy (Exact) Tr. 1742).
2022. The CancerSEEK test used in the Cohen study tested “positive in a median of 70% of the eight cancer types. The sensitivities ranged from 69 to 98 percent for the detection of five cancer types (ovary, liver, stomach, pancreas, and esophagus) for which there are no screening tests available for average-risk individuals.” (RX3142 at 001 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).
2023. The Cohen study acknowledged that the patient cohort was comprised of individuals who had been diagnosed with stage I to III cancers of the ovary, liver, stomach, pancreas, esophagus, colorectum, lung, or breast. (RX3142 at 002 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018 (49% of patients had stage II cancer; 20% of patients had stage I cancer; and 31 % of patients had stage III cancer.); Conroy (Exact) Tr. 1701).
2024. The Cohen study used a “healthy control cohort” of “812 individuals of median age 55 (range 17 to 88) with no known history of cancer, high-grade dysplasia, auto-immune disease, or chronic kidney disease.” (RX3142 at 002 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).
2025. The eight cancer types were chosen because they are common in western populations and because no blood-based tests for their earlier detection are in common clinical use. (RX3142 at 001 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).
2026. The researchers in the Cohen study estimated that the sensitivity of CancerSEEK was 55 percent among all eight cancer types selected. (Conroy (Exact) Tr. 1702-03; RX3142 at

004 (Cohen et. al, Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, Feb. 23, 2018)).

b) The DETECT-A Study

2027. The second CancerSEEK study was “DETECT-A.” (Conroy (Exact) Tr. 1703-04).
2028. The results of DETECT-A were published in July 2020 in Science Magazine, a prominent peer-reviewed scientific journal, under the title, “Feasibility of blood testing combined with PET-CT to screen for cancer and guide intervention.” (Conroy (Exact) Tr. 1703; Lengauer (Third Rock Ventures) Tr. 164-65; RX3419 (Lennon et al., Feasibility of Blood Testing Combined with PET-CT to Screen for Cancer and Guide Intervention, *Science* 369, 49 (2020))).
2029. [REDACTED] } (PX7085 (Harada (Exact) Dep. at 20) (*in camera*)).
2030. Thrive completed a large interventional study of CancerSEEK involving the multi-cancer screening of 10,000 women called DETECT-A. (Lengauer (Third Rock Ventures) Tr. 163-65; Conroy (Exact) Tr. 1704).
2031. DETECT-A was an exploratory prospective interventional study. (Conroy (Exact) Tr. 1703).
2032. Dr. Lengauer testified that DETECT-A was the largest and only interventional study in the screening setting of a multicancer test. (Lengauer (Third Rock Ventures) Tr. 164).
2033. An interventional study involves testing patients, getting results, and giving those results back to the physician and patient. (Lengauer (Third Rock Ventures) Tr. 164).
2034. Dr. Lengauer testified at trial that Thrive is the only MCED test developer to conduct an interventional study. (Lengauer (Third Rock Ventures) Tr. 164).
2035. The purpose of Thrive’s DETECT-A study was to understand the sensitivity, specificity, and safety of its CancerSEEK test, as well as how it fits within the existing physician workflow. (Lengauer (Third Rock Ventures) Tr. 165).
2036. Dr. Lengauer testified that specificity “is a measure that relates to how frequently one generates false-positives, or in other words, a false alarm; for example, if you were to say you have cancer, but it ends up being that there is no cancer.” (Lengauer (Third Rock Ventures) Tr. 166).
2037. The specificity of CancerSEEK was measured in the DETECT-A study at “a little bit over 99 percent, which is an important requirement for a screening test of asymptomatic individuals.” (Lengauer (Third Rock Ventures) Tr. 166-67).

2038. Dr. Lengauer explained that specificity is an important requirement because CancerSEEK “is designed for individuals that are asymptomatic, which means individuals that would go to their annual exam, not that they have cancer by any means, and in that context get this test. In such a group it is very, very important that we are not causing false alarm because there are consequences.” These consequences include a follow up doctor visit and interventional methods such as biopsies and other forms of surgeries to try and find the cancer after a positive screening test result. Thus, “in an asymptomatic – or maybe we call it in lay terms healthy population – when you apply a test, it’s extremely important that the false-positives that such a test cause are very, very rare.” (Lengauer (Third Rock Ventures) Tr. 167).
2039. Dr. Lengauer testified that sensitivity means “what’s the fraction of cancers that one can identify from all the cancers that are out there in principle.” (Lengauer (Third Rock Ventures) Tr. 166768).
2040. The sensitivity of CancerSEEK was measured in the DETECT-A study across all cancer types. DETECT-A makes a determination of “sensitivity for an interventional cancer type that relates to a certain organ, like breast or colon.” (Lengauer (Third Rock Ventures) Tr. 168).
2041. “Today, only 25 percent of cancers can be detected by screening methods. 75 percent of cancers are detected by symptoms, signs and symptoms, which means cancers are usually detected late.” (Lengauer (Third Rock Ventures) Tr. 168-69).
2042. The outcome of the DETECT-A study “showed that now 52 percent, which means – of cancers can be detected by screening first, which means we can now double the number[ ] of cancers first detected by screening, which means cancer in most individuals can be detected now earlier.” (Lengauer (Third Rock Ventures) Tr. 169).
2043. Dr. Lengauer testified that the DETECT-A study provided Thrive with a “good understanding about the performance of the [CancerSEEK] test.” The results can be “summarized by saying that [CancerSEEK] could [ ] more than double the cancers detected... compared to the classical standard of screening methods.” (Lengauer (Third Rock Ventures) Tr. 165-66).
2044. The DETECT-A study also showed that CancerSEEK “is very safe” and how the integration of CancerSEEK into clinical care “had no impact on compliance to the standard of care, which is a very important from a safety perspective.” (Lengauer (Third Rock Ventures) Tr. 166).
2045. Overall the DETECT-A study showed how well CancerSEEK “integrates [ ] into the work flow of physicians.” (Lengauer (Third Rock Ventures) Tr. 166).
2046. DETECT-A used a three-step testing process: a baseline blood test, a confirmation blood test, and then imaging using a PET-CT scan. (Conroy (Exact) Tr. 1704; RX3419 (Lennon et al., Feasibility of Blood Testing Combined with PET-CT to Screen for Cancer and Guide Intervention, *Science* 369, 49 (2020))).

2047. DETECT-A’s baseline blood test was an early version of CancerSEEK. (Conroy (Exact) Tr. 1704).
2048. DETECT-A’s confirmation blood test was given to participants that scored positive on the baseline blood test. (Conroy (Exact) Tr. 1704).
2049. DETECT-A used a diagnostic PET-CT scan to confirm the results of CancerSEEK and localize the potential cancer. (Conroy (Exact) Tr. 1704).
2050. CancerSEEK identified ten types of cancer in DETECT-A: appendix, breast, carcinoma, unknown primary origin, colorectal, kidney, lung, lymphoma, ovary, thyroid, and uterine. (Conroy (Exact) Tr. 1706).
2051. The DETECT-A study showed that CancerSEEK could more than double the cancers detected by standard screening methods. (Lengauer (Third Rock Ventures) Tr. 165-66).
2052. The DETECT-A study showed that CancerSEEK is safe and integrated into clinical care in a way that had no impact on compliance with standard of care screening. (Lengauer (Third Rock Ventures) Tr. 165-66).
2053. The DETECT-A study established that CancerSEEK’s specificity was over 99 percent. (Lengauer (Third Rock Ventures) Tr. 166-67).
2054. The DETECT-A study established that CancerSEEK’s sensitivity was 52 percent, detecting double the number of cancers first detected by standard screening methods. (Lengauer (Third Rock Ventures) Tr. 168-69).
2055. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 273-74 (*in camera*)).
2056. In an email dated April 30, 2020, Ammar Qadan, Illumina’s Vice President and Global Head of Market Access, explained that “[t]he data published in Science about the Thrive test shows a very carefully designed study in many ways.” (PX2731 (Illumina) at 001 (Email from A. Qadan, Illumina, to J. Goswami, Illumina, Apr. 30, 2020) (adding “These guys know exactly what they’re doing.”) .
2057. Mr. Qadan explained in an email that, “In my humble opinion, the above could accelerate the Thrive test approval process and uptake as it is very defined[.]” (PX2731 (Illumina) at 001 (Email from A. Qadan, Illumina, to J. Goswami, Illumina, Apr. 30, 2020)).
2058. Since the DETECT-A study, Thrive has continued to improve CancerSEEK. (Lengauer (Third Rock Ventures) Tr. 169-70).
2059. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 187-88 (*in camera*)).

2060. After DETECT-A, Thrive plans to further improve its test and are preparing for a registrational trial. (Lengauer (Third Rock Ventures) Tr. 169-70).

c) [REDACTED]

2061. [REDACTED] } (Conroy (Exact) Tr. 1632-33 (*in camera*)).

2062. [REDACTED] } (Conroy, (Exact) Tr. 1633 (*in camera*)).

2063. [REDACTED] } (Conroy (Exact) Tr. 1633 (*in camera*)).

2064. [REDACTED] (Conroy (Exact) Tr. 1564 (*in camera*)).

2065. [REDACTED] } (Conroy (Exact) Tr. 1564) (*in camera*)).

2066. [REDACTED] } (Conroy (Exact) Tr. 1564 (*in camera*)).

2067. [REDACTED] } (Conroy (Exact) Tr. 1564 (*in camera*)).

2068. [REDACTED] } (Conroy (Exact) Tr. 1633 (*in camera*)).

d) [REDACTED]

2069. For FDA approval, test developers undergo a “registrational trial,” which allows the FDA to evaluate the benefits-to-risk ratio of a test or device. (Lengauer (Third Rock Ventures) Tr. 170).

2070. [REDACTED] (Conroy (Exact) Tr. 1634 (*in camera*)).

2071. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 189-190 (*in camera*)).

2072. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 1190-91 (*in camera*)).

2073. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 189-90 (*in camera*)).

2074. [REDACTED]  
[REDACTED] (Conroy (Exact) Tr. 1559-60 (*in camera*)).
2075. [REDACTED]  
[REDACTED] } (PX7091 (Lengauer (Third Rock Ventures) Dep. at 137) (*in camera*)).
2076. [REDACTED]  
[REDACTED] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 137-38) (*in camera*)).
2077. [REDACTED] } (Conroy, (Exact) Tr. 1634 (*in camera*)).
2078. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 190 (*in camera*); PX7085 (Harada (Exact) Dep. at 176-77) (*in camera*); PX7091 (Lengauer (Third Rock Ventures) Dep. at 82) (*in camera*); PX8317 (Exact) at 022 [REDACTED] (*in camera*)).
2079. [REDACTED]  
[REDACTED] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 134) (*in camera*)).
2080. [REDACTED]  
[REDACTED] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 134) (*in camera*)).
2081. [REDACTED]  
[REDACTED] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 134) (*in camera*)).
2082. [REDACTED]  
[REDACTED] } (PX7091 (Lengauer (Third Rock Ventures) Dep. at 135) (*in camera*)).
2083. [REDACTED]  
[REDACTED] (Conroy (Exact) Tr. 1634 (*in camera*)).
2084. [REDACTED]  
[REDACTED] (Lengauer (Third Rock Ventures) Tr. 193 (*in camera*)).
2085. [REDACTED]  
[REDACTED] (Lengauer (Third Rock Ventures) Tr. 192-93 (*in camera*)).

2086. In a prospective study, the patient gets a blood tube drawn before being diagnosed with cancer. (Conroy (Exact) Tr. 1744-45).
2087. A prospective study will then use another means of determining whether the patient has cancer. (Conroy (Exact) Tr. 1744-45).
2088. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 192-93 (*in camera*)).
2089. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 192-93 (*in camera*)).
2090. According to Mr. Conroy, Grail’s previous studies have been case-controlled retrospective studies. (Conroy (Exact) Tr. 1743).
2091. A case-controlled study is “a study where samples are collected from patients after they’ve already been diagnosed with disease.” (Conroy (Exact) Tr. 1744).
2092. Mr. Conroy testified that, in case-controlled studies, sensitivity is “typically significantly better because the cases that you find are typically later stage[.]” (Conroy (Exact) Tr. 1744-45).
2093. Mr. Conroy testified at trial that it is unfair to compare the sensitivity results of a prospective study to a case-control study because case-control studies almost always have higher sensitivities and typically slightly better specificities than a prospective study. (Conroy (Exact) Tr. 1745).
2094. The SOAR study has a different trial design from the Cohen study and DETECT-A. (Conroy (Exact) Tr. 1742-43).
2095. The DETECT-A study and the SOAR study differ because the DETECT-A study only examined women in one health system. (Conroy (Exact) Tr. 1742-43).
2096. The DETECT-A study was a smaller study than SOAR. (Conroy (Exact) Tr. 1742-43).
2097. Grail is in the process of doing a prospective study in a high-risk population. (Conroy (Exact) Tr. 1743).
2098. Mr. Conroy testified that Grail’s prospective study will have a narrower population than that of the DETECT-A study. (Conroy (Exact) Tr. 1743).
2099. [REDACTED] (Conroy (Exact) Tr. 1560 (*in camera*)).

2100. [REDACTED] }  
(Conroy (Exact) Tr. 1559 (*in camera*)).

2101. [REDACTED]  
[REDACTED] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 135) (*in camera*)).

2102. [REDACTED]  
[REDACTED]  
[REDACTED] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 135-36) (*in camera*)).

2103. [REDACTED]  
[REDACTED] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 139) (*in camera*)).

2104. [REDACTED]  
[REDACTED] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 140-41) (*in camera*)).

6. [REDACTED] }

2105. [REDACTED] } (PX7091 (Lengauer (Third Rock Ventures) Dep. at 87) (*in camera*)).

2106. [REDACTED]  
[REDACTED] (PX7091 (Lengauer (Third Rock Ventures) Dep. at 87) (*in camera*)).

2107. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 52) (*in camera*))  
[REDACTED] )).



2108. [REDACTED] (PX7110 (Conroy (Exact) Dep. at 48) (*in camera*); PX8572 (Exact) at 033 (Exact, Innovation & Technology Committee Spring Meeting Presentation, Apr. 16, 2020) (*in camera*)).

2109. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 50-51) (*in camera*); PX7058 (Conroy (Exact) IHT at 80-82) (*in camera*)).

2110. [REDACTED]  
[REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 50-51) (*in camera*)).

2111. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 88) (*in camera*)).

**7. Prior to Acquiring Thrive and CancerSEEK, Exact Conducted MCED Research & Development, Dating Back to 2009**

2112. Exact's principal collaboration for research and development efforts is with the Mayo Clinic. (Conroy (Exact) Tr. 1536-37).

2113. The Exact-Mayo Clinic partnership started in June 2009. (Conroy (Exact) Tr. 1536-37; PX7110 (Conroy (Exact) Dep. at 10) (*in camera*)).

2114. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 10) (*in camera*)).

2115. [REDACTED]  
[REDACTED] (PX7110 (Conroy (Exact) Dep. at 10) (*in camera*)).

2116. The Exact-Mayo Clinic partnership has continued for 12 years. (Conroy (Exact) Tr. 1536-37).

2117. Dr. Dave Ahlquist was a gastroenterologist at Mayo Clinic. (Conroy (Exact) Tr. 1538-39).

2118. Dr. Ahlquist participated in the Exact-Mayo Clinic partnership. (Conroy (Exact) Tr. 1539-40).

2119. Mr. Conroy explained that Dr. Ahlquist's work was integral to Exact's product development. (Conroy (Exact) Tr. 1539-41).

2120. Dr. Ahlquist conducted research for years on colon cancer screening. (Conroy (Exact) Tr. 1538-39).
2121. Dr. Ahlquist looked for biomarkers that could identify colon cancer early. (Conroy (Exact) Tr. 1538-39).
2122. Dr. Ahlquist looked for these colon cancer biomarkers in stool, blood, and other patient samples. (Conroy (Exact) Tr. 1538-39).
2123. Dr. Ahlquist’s research looked at data demonstrating the ability to detect colon cancer and even precancerous polyps accurately from a stool sample. (Conroy (Exact) Tr. 1539).
2124. In March 2009, Dr. Ahlquist told Exact CEO, Mr. Conroy, of his vision for detecting many or most cancers from a simple blood draw. (Conroy (Exact) Tr. 1539).
2125. Dr. Ahlquist called this vision a “pan-cancer” test, which would look for tiny fragments of cancer DNA in a patient’s blood. (Conroy (Exact) Tr. 1539-40).
2126. Dr. Ahlquist’s vision for a pan-cancer test became the genesis of Exact’s mission to detect cancer earlier. (Conroy (Exact) Tr. 1540).
2127. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 53-54) (*in camera*)).
2128. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 53-54) (*in camera*)).
2129. [REDACTED] (PX7058 (Conroy (Exact) IHT at 54) (*in camera*)).
2130. Exact has a development partnership with City of Hope. (Conroy (Exact) Tr. 1536-37).
2131. Exact has a partnership with Johns Hopkins University. (Conroy (Exact) Tr. 1536-37).
2132. Thrive has a collaboration agreement with Johns Hopkins University and Howard Hughes Medical Institute that involves sharing research between the organizations. (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 37-38)).
2133. Exact is in the process of combining CancerSEEK with Exact and Dr. Ahlquist’s biomarker research to bring the best of both of those technologies together to develop the best, most accurate MCED test for physicians and patients. (Conroy (Exact) Tr. 1543).

**8. Background on Exact Sciences' Oncology Start-Up Pedigree: Product Development, Regulatory Success, and Salesforce Expansion**

a) Exact's Cologuard Test

2134. The first test Exact developed was Cologuard. (PX7058 (Conroy (Exact) IHT at 20)).
2135. Exact has screened over 6 million people with its colon cancer screening test, Cologuard. (Conroy (Exact) Tr. 1541).
2136. Of the 6 million Cologuard patients, approximately 200,000 people found precancerous polyps and had those polyps removed. (Conroy (Exact) Tr. 1541).
2137. Of the 6 million Cologuard patients, approximately 30,000 people have been diagnosed with early, treatable-stage colon cancer versus later stage. (Conroy (Exact) Tr. 1541).
2138. The goal of Cologuard is "to shift detection from late stage, which is largely where colon cancer is detected today, to early stage," where it frequently can be surgically cured without chemotherapy. (Conroy (Exact) Tr. 1540).
2139. Cologuard is an FDA-approved test. (Conroy (Exact) Tr. 1547; PX6049 (Grail) at 036  
[REDACTED])
2140. Cologuard was the first product for which Exact obtained FDA approval. (Conroy (Exact) Tr. 1547).
2141. To receive FDA approval for Cologuard, Exact ran a 10,000-patient study where every patient underwent a colonoscopy, took a Cologuard test, and took a fecal immunochemical test. (Conroy (Exact) Tr. 1547-48).
2142. In the Cologuard 10,000 patient study, Exact was able to demonstrate the accuracy of Cologuard and the relative accuracy of its fecal immunochemical ("FIT") test. (Conroy (Exact) Tr. 1547-48).
2143. Exact submitted the data from the Cologuard study in its PMA application to the FDA. (Conroy (Exact) Tr. 1547-48).
2144. The Cologuard 10,000 patient study took over two years to complete. (Conroy (Exact) Tr. 1547-48).
2145. To receive FDA approval for Cologuard, Exact provided extensive information to the FDA. (Conroy (Exact) Tr. 1548).
2146. Exact was required to provide the FDA information about Cologuard's third-party suppliers. (Conroy (Exact) Tr. 1548-49).

2147. The FDA inspected Guardant’s “key suppliers,” who are “critical” to the FDA approval process. (Conroy (Exact) Tr. 1548-49).

2148. Mr. Conroy testified at trial that “key suppliers are inspected by the FDA to help ensure that the quality measures are put into place and being followed prior to FDA approval and since FDA approval.” (Conroy (Exact) Tr. 1548-49).

2149. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 29) (*in camera*)).

2150. [REDACTED] } (Conroy (Exact) Tr. 1629 (*in camera*)).

2151. [REDACTED] (PX7058 (Conroy (Exact) IHT at 27-28) (*in camera*)).

2152. “[T]he American Cancer Society and the U.S. Preventive Services Task Force did include Cologuard in those screening guidelines.” (PX7058 (Conroy (Exact) IHT at 21)).

2153. In June 2016, the USPSTF issued its final guidance document which approved Cologuard. (PX7058 (Conroy (Exact) IHT at 33)).

2154. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 28-29) (*in camera*)).

2155. [REDACTED] (PX7058 (Conroy (Exact) IHT at 29) (*in camera*)). [REDACTED] )).

2156. [REDACTED]

[REDACTED] } (PX7110 (Conroy (Exact) Dep. at 60-62) (*in camera*)).

2157. When Exact went through the regulatory and reimbursement process for Cologuard, it was the first time Exact had ever gone through the regulatory process. (PX7058 (Conroy (Exact) IHT at 33)).

2158. [REDACTED] (PX7110 (Conroy (Exact) Dep. at 62-63) (*in camera*)).

2159. [REDACTED] (PX7058 (Conroy (Exact) IHT at 58) (*in camera*)).

b) Exact Used Multiple Consultants to Aid Its Regulatory Approval

2160. To facilitate Cologuard’s FDA approval, Exact worked with many regulatory consultants and biostatisticians who know the FDA process well. (Conroy (Exact) Tr. 1549-50; see PX7110 (Conroy (Exact) Dep. at 26-28) (*in camera*) ([REDACTED] )).

2161. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 27) (*in camera*)).

2162. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 27) (*in camera*)).

2163. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 28) (*in camera*)).

2164. Exact’s consultants helped Exact set up quality systems as part of the FDA process. (Conroy (Exact) Tr. 1549-50).

2165. Exact decided to use consultants for the FDA process because these consultants are experts in working with the FDA, and it is “very hard to do that just internally.” (Conroy (Exact) Tr. 1550).

2166. At trial, Mr. Conroy pointed to Exact’s use of a biostatistician consultant as “critical” to Cologuard’s FDA review: “For example, our biostatistician was somebody who had been in front of 50 FDA panel meetings. And we have never been in front of a panel meeting, so getting that type of input and support and help is just critical to having a smooth working relationship with FDA.” (Conroy (Exact) Tr. 1550).

2167. These consultants helped “accelerate” and “enable” Cologuard’s FDA approval process. (Conroy (Exact) Tr. 1550).

2168. [REDACTED]  
[REDACTED] } (PX7110 (Conroy (Exact) Dep. at 28) (*in camera*)).

c) Exact Built its Salesforce from Scratch, Expanding as Cologuard Received Regulatory Approvals and Reimbursement Status

2169. Today, Exact is a commercial company that has teams of people who educate healthcare providers about the tests Exact offers and provides clinical testing services. (Conroy (Exact) Tr. 1532-33).

2170. Exact has a clinical sales force. (Conroy (Exact) Tr. 1534).

2171. [REDACTED]  
[REDACTED] } (PX7110 (Conroy (Exact) Dep. at 41-42) (*in camera*)).

2172. [REDACTED]  
[REDACTED] } (PX7110 (Conroy (Exact) Dep. at 42) (*in camera*)).

2173. [REDACTED] (PX7058  
(Conroy (Exact) IHT at 36-37) (*in camera*)).

2174. [REDACTED]  
[REDACTED] } (PX7058 (Conroy (Exact) IHT at 36-37) (*in camera*)).

2175. [REDACTED] (PX7058 (Conroy (Exact) IHT at 37) (*in camera*)).

2176. [REDACTED] (PX7058 (Conroy (Exact) IHT at 37) (*in camera*)).

2177. [REDACTED] (PX7058 (Conroy (Exact) IHT at 37) (*in camera*)).

2178. [REDACTED]

2179. [REDACTED]

2180. [REDACTED]

2181. [REDACTED]

2182. [REDACTED]

2183. [REDACTED]

2184. [REDACTED]

9. [REDACTED]

[REDACTED]

B. [REDACTED]

1. [REDACTED]

2185. [REDACTED]

2186. [REDACTED]

2187. [REDACTED]

2188. [REDACTED]

2189. [REDACTED]

2190. [REDACTED]

2191. [REDACTED]

2192. [REDACTED]

2193. [REDACTED]

2194. [REDACTED]

2195. [REDACTED]

2196. [REDACTED]

2197. [REDACTED]

2198. [REDACTED]

2199. [REDACTED]

2200. [REDACTED]

2201. [REDACTED]



2202. [REDACTED]

2203. [REDACTED]

2204. [REDACTED]

2205. [REDACTED]

2206. [REDACTED]

2207. [REDACTED]

2. [REDACTED]

2208. [REDACTED]

2209. [REDACTED]

2210. [REDACTED]

2211. [REDACTED]

2212. [REDACTED]

2213. [REDACTED]

2214. [REDACTED]

2215. [REDACTED]

3. [REDACTED]

2216. [REDACTED]

2217. [REDACTED]

2218. [REDACTED]

2219. [REDACTED]

2220. [REDACTED]

2221. [REDACTED]

2222. [REDACTED]

2223. [REDACTED]

2224.

[REDACTED]

2225.

[REDACTED]

2226.

[REDACTED]

2227.

[REDACTED]

2228.

[REDACTED]

2229.

[REDACTED]

2230.

[REDACTED]

2231.

[REDACTED]

2232.

[REDACTED]

2233.

[REDACTED]

2234. [REDACTED]

2235. [REDACTED]

2236. [REDACTED]

2237. [REDACTED]

2238. [REDACTED]

2239. [REDACTED]

2240. [REDACTED]

4. [REDACTED]

2241. [REDACTED]

2242. [REDACTED]

2243. [REDACTED]

2244. [REDACTED]

2245. [REDACTED]

2246. [REDACTED]

2247. [REDACTED]

2248. [REDACTED]

2249. [REDACTED]

5. [REDACTED]

2250. [REDACTED]

2251. [REDACTED]

2252. [REDACTED]

2253. [REDACTED]

2254. [REDACTED]

2255. [REDACTED]

[REDACTED]

2256.

[REDACTED]

6.

[REDACTED]

[REDACTED]

**C. GUARDANT HEALTH IS DEVELOPING AN MCED TEST CALLED LUNAR-2**

**1. Guardant Is An Established Oncology Test Developer**

2257. Guardant—a publicly traded company—is headquartered in Redwood City, California. (PX0059 (Guardant) at 001 (Guardant Health FY 2019 Form 10-K)).

2258. Guardant is a clinical diagnostics company that is currently developing blood-based tests for oncology applications. (Chudova (Guardant) Tr. 1135).

2259. Guardant’s mission is “to conquer cancer with data.” (Getty (Guardant) Tr. 2488).

2260. Guardant’s R&D efforts include three oncology related clinical applications: a therapy selection test, a minimal residual disease test, and a cancer screening test. (Chudova (Guardant)Tr. 1138-39). These three applications span the different phases of a cancer diagnosis, from an undiagnosed patient to patients currently undergoing various stages of treatment. (Chudova (Guardant) Tr. 1138-39).

2261. Guardant’s flagship product, Guardant360, is a therapy selection test that helps clinicians choose the appropriate treatment for patients diagnosed with cancer based on an analysis of a blood sample. (Chudova (Guardant) Tr. 1146-47).

2262. Guardant obtained breakthrough device status for Guardant 360 CDx on January 29, 2018. (PX8316 (Guardant) at 001 (Summary of Safety and Effectiveness Data (SSED), Dec. 21, 2020)).

2263.

[REDACTED]

} (See PX2046 (Illumina) (Email from P. Febbo, Illumina, to J. Leite, Illumina, et al, discussing Guardant 360 CDx FDA approval Cowen Press Release, Aug. 10, 2020) (*in camera*); RX3299 (FDA, Guardant360 CDx – P200010,

<https://www.fda.gov/medical-devices/recently-approved-devices/guardant360-cdx-p200010> (last visited Feb. 10, 2022)); PX7045 (Chudova (Guardant) IHT at 17-18)).

- 2264. Guardant’s therapy selection oncology application helps identify biomarkers that can be used to match cancer patients with relevant treatment options. (Chudova (Guardant) Tr. 1138-39).
- 2265. LUNAR-1 is currently in clinical trials to obtain FDA approval. (PX7045 (Chudova (Guardant) IHT at 68-69)).
- 2266. [REDACTED] } (PX7040 (Getty (Guardant) IHT at 114) (*in camera*)).
- 2267. Dr. Chudova testified that Guardant plans to extend Guardant Reveal to detect additional cancers beyond colorectal and will launch a new version of the test with additional cancers shortly. (Chudova (Guardant) Tr. 1152).
- 2268. Guardant is developing early-stage cancer screening products with a current focus on screening for colorectal cancer. (PX7045 (Chudova (Guardant) IHT at 17-19)).
- 2269. At trial, Dr. Chudova described Guardant’s development of a cancer screening test as a “big area of development at the moment” for the company. (Chudova (Guardant) Tr. 1152).
- 2270. Each of Guardant’s clinical tests in development uses NGS sequencing in its workflow. (Chudova (Guardant) Tr. 1139-40).
- 2271. Illumina is Guardant’s sole supplier of sequencer instruments and the sole supplier of repair services for Guardant’s sequencer instruments. (Getty (Guardant) Tr. 2683).

**2. Guardant Is Developing an MCED Test Called LUNAR-2**

- 2272. Guardant has spent several years developing a cancer screening test based on the technological platform used for its Guardant Reveal MRD test. (Chudova (Guardant) Tr. at 1152).
- 2273. [REDACTED] } (Getty, Tr. 2493-94; PX7100 (Chudova (Guardant) Dep. at 15-16); PX7045 (Chudova (Guardant) IHT at 17-19)).
- 2274. [REDACTED] } (PX7105 (Getty (Guardant) Dep. at 13-14) (*in camera*)).
- 2275. [REDACTED] (Chudova (Guardant) Tr. 1243 (*in camera*)).

2276. [REDACTED]  
(Chudova (Guardant) Tr. 1243 (*in camera*)).
2277. Dr. Chudova testified at trial that she is “focused on developing technology that could be used for detection of multiple cancer indications or precancer indications, any cancer.” (Chudova (Guardant) Tr. 1179).
2278. Guardant’s cancer screening test is suitable for multiple cancer types. (Chudova (Guardant) Tr. 1179).
2279. Guardant’s business strategy involves first creating a colorectal cancer (“CRC”) test that will be rapidly adopted, then moving to a multi-cancer phase. (Getty (Guardant) Tr. 2495-96; *see* Chudova (Guardant) Tr. 1153-54 (stating that the initial version of Guardant’s cancer screening test will screen for colorectal cancer)).
2280. Dr. Chudova testified that the benefit of prioritizing cancers with existing screening modalities is that “clinically it’s established that screening for those indications is beneficial for the patients.” (Chudova (Guardant) Tr. 1153-54).
2281. [REDACTED]  
[REDACTED] (PX7090 (Sood (Guardant) Dep. at 108) (*in camera*)).
2282. For its MCED test, Guardant is initially focusing on cancers with existing screening modalities—including colorectal, lung, and breast cancer. (Chudova (Guardant) Tr. 1153-54; Getty (Guardant) Tr. 2499).
2283. Dr. Chudova testified at trial that the benefits of prioritizing cancers with existing screening modalities is “clinically it’s established that screening for those indications is beneficial for the patients.” (Chudova (Guardant) Tr. 1153-54).
2284. As Mr. Getty explained, starting with CRC makes “it a little bit easier to bring a test to market in a faster fashion,” and Guardant’s strategy of “pursuing a singular tumor and then adding on tumors is just a little bit of a different view of the same coin that Grail has.” (PX7105 (Getty (Guardant) Dep. at 238)).
2285. [REDACTED]  
[REDACTED] (PX8503 (Guardant) at 066 [REDACTED]) (*in camera*).
2286. [REDACTED]  
[REDACTED] (Getty (Guardant) Tr. 2565-66, 2569-70 (*in camera*)).



2287. Guardant plans to initiate MCED test clinical trials in the near future. (Getty (Guardant) Tr. 2497).
2288. Guardant’s primary customer for its MCED test will be the primary care physician, including OB/GYN physicians who function as the primary caregiver for women. (Getty (Guardant) Tr. 2502).
2289. The initial version of Guardant’s cancer screening test will screen for colorectal cancer (“CRC”). (Chudova (Guardant) Tr. 1153-54).
2290. Guardant’s business strategy involves first creating a CRC test that will be rapidly adopted, then moving to a multi-cancer phase. (Getty (Guardant) Tr. 2495-96).
2291. [REDACTED] (Getty (Guardant) Tr. 2625 (*in camera*)).
2292. [REDACTED] (PX7100 (Chudova (Guardant) Dep. at 22-23) (*in camera*)).
2293. Guardant is currently conducting a clinical trial—called Eclipse—on the use of its screening test for colorectal cancer. (Chudova (Guardant) Tr. 1154-55).
2294. [REDACTED] } (PX7040 (Getty (Guardant) IHT at 149) (*in camera*)).
- a) Guardant’s MCED Test Is Based off the Technological Platform Used with Guardant Reveal
2295. Guardant has spent several years developing its cancer screening test based on the technological platform used with its MRD test. (Chudova (Guardant) Tr. 1152).
2296. [REDACTED] (PX7100 (Chudova (Guardant) Dep. at 23-24) (*in camera*)).
2297. [REDACTED] } (Getty (Guardant) Tr. 2628 (*in camera*)).
2298. As Dr. Chudova explained, for LUNAR-2, “The platform in its foundation doesn’t have anything specific for an individual cancer types other than the selection of the regions of the genomes that are most representative for that specific cancer. But that’s a minor aspect of the technology, and it can be adapted to other cancer types.” (PX7100 (Chudova (Guardant) Dep. at 24)).

2299. [REDACTED]

(PX7105 (Getty (Guardant) Dep. at 132-33) (*in camera*)).

2300. Dr. Chudova testified that “Guardant has active plans to apply technology that we’ve developed for colorectal cancer to . . . multi-cancer screening context that involves cancers other than colorectal cancer.” (PX7100 (Chudova (Guardant) Dep. at 23-24)).

2301. [REDACTED]

} (PX7045 (Chudova (Guardant) IHT at 100) (*in camera*)).

2302. [REDACTED]

(PX7100 (Chudova (Guardant) Dep. at 107) (*in camera*)).

2303. [REDACTED]

(PX7100 (Chudova (Guardant) Dep. at 139) (*in camera*)).

2304. [REDACTED]

(PX7105 (Getty (Guardant) Dep. at 199-200) (*in camera*)).

b) [REDACTED]

2305. [REDACTED]

(PX7105 (Getty (Guardant) Dep. at 23); Chudova Tr. 1199-1200 (*in camera*); *see also* PX7100 (Chudova (Guardant) Dep. at 23-24, 147-48) (*in camera*)).

2306. [REDACTED]

(Chudova (Guardant) Tr. 1200 (*in camera*)).

2307. [REDACTED]

(Chudova (Guardant) Tr. 1201 (*in camera*)).

2308. [REDACTED]  
(PX8503 (Guardant) at 066 [REDACTED] (in camera)).

2309. [REDACTED]  
(PX8503 (Guardant) at 066 [REDACTED] (in camera)).

2310. [REDACTED]  
} (Getty (Guardant) Tr. 2533, 2537 (in camera)).

2311. [REDACTED]  
} (Getty (Guardant) Tr. 2533-34 (in camera)).

2312. [REDACTED]  
} (Chudova (Guardant) Tr. 1309-10 (in camera)).

2313. [REDACTED]  
(Chudova (Guardant) Tr. 1309-11 (in camera)).

2314. [REDACTED]  
(Chudova (Guardant) Tr. 1200-01 (in camera)).

2315. [REDACTED]  
(Chudova (Guardant) Tr. 1205 (in camera)).

2316. [REDACTED]  
} (PX7100 (Chudova (Guardant) Dep. at 150-51) (in camera)).

2317. Dr. Chudova testified at trial that Guardant’s products “have been generating development data to [ ] date that suggests that [Guardant] will have a decent chance in being successful in this very, very complicated endeavor” of developing a cancer screening test. (Chudova (Guardant) Tr. 1154-55).

3. [REDACTED]

2318. [REDACTED]  
(Getty (Guardant) Tr. 2529 (in camera); PX7040 (Getty (Guardant) IHT at 149) (in camera)).

2319. [REDACTED] } (PX8503 (Guardant) at 065 (in camera)). [REDACTED] } (PX8503 (Guardant) at 065 (in camera)); see PX7100 (Chudova (Guardant) Dep. at 137-38) (in camera) ( [REDACTED] })).

2320. [REDACTED] } (PX8309 (Guardant) at 011 (in camera)).

2321. [REDACTED] (Getty (Guardant) Tr. 2505, 2529 (in camera)).

2322. [REDACTED] } (PX8309 (Guardant) at 016 (in camera)).

2323. [REDACTED] (Chudova (Guardant) Tr. 1206 (in camera)).

2324. [REDACTED] } (Chudova (Guardant) Tr. 1202 (in camera)).

**4. Guardant Is Committed to Improving Its MCED Test Over Time**

2325. [REDACTED] } (Getty (Guardant) Tr. 2537-38 (in camera)).

2326. [REDACTED] (Getty (Guardant) Tr. 2539-40 (in camera)).

2327. [REDACTED] (Getty (Guardant) Tr. 2540 (in camera)).

2328. Continually improving the performance of an MCED test will “catch more early stage disease” before it becomes aggressive and spreads, as well as “save [patients] the mental anguish of telling them they have a disease” when they do not. (PX7105 (Getty (Guardant) Dep. at 29-30)).

2329. [REDACTED] (Getty, Tr. 2540 (*in camera*); PX7090 (Sood (Guardant) Dep. at 108); PX7100 (Chudova (Guardant) Dep. at 27)).

2330. [REDACTED] } (Getty (Guardant) Tr. 2540 (*in camera*)).

2331. Mr. Getty testified regarding his expectation that a distributed model of cancer screening tests will be “important” and “oftentimes the preferred mode in certain markets, for certain customers.” (PX7040 (Getty (Guardant) IHT at 162-163); *see* PX7105 (Getty (Guardant) Dep. at 246) (testifying a distributed model for its MCED test is “certainly something that we would have to explore at some point if the market conditions effectively pushed us in that direction.”)).

2332. Mr. Getty explained that Guardant “would need to work with Illumina” in order to obtain FDA approval to sell Guardant’s MCED test as a distributed IVD test. (Getty (Guardant) Tr. 2689).

5. [REDACTED]

2333. [REDACTED]

2334. [REDACTED] (Chudova (Guardant) Tr. 1156; PX7100 (Chudova (Guardant) Dep. at 127-28) (*in camera*)).

2335. [REDACTED] } (PX7100 (Chudova (Guardant) Dep. at 31-32, 131) (*in camera*)).

2336. [REDACTED]

2337. [REDACTED] (Chudova (Guardant) Tr. 1155).

2338. [REDACTED] } (PX7100 (Chudova (Guardant) Dep. at 34) (*in camera*)).

2339. [REDACTED] (PX7100 (Chudova (Guardant) Dep. at 34) (*in camera*)).

2340. [REDACTED]  
[REDACTED] (PX7100 (Chudova (Guardant) Dep. at 34-35) (*in camera*)).

2341. [REDACTED] (Getty (Guardant) Tr. 2534-35 (*in camera*)).

2342. [REDACTED]  
[REDACTED] (Chudova (Guardant) Tr. 1200 (*in camera*)).

2343. [REDACTED] } (Chudova (Guardant) Tr. 1200 (*in camera*)).

2344. [REDACTED] } (Chudova (Guardant) Tr. 1154-55, 1201) (*in camera*)).

2345. [REDACTED] (Chudova (Guardant) Tr. 1202 (*in camera*); PX7105 (Getty (Guardant) Dep. at 167) ([REDACTED]) (*in camera*)).

2346. [REDACTED] } (Chudova (Guardant) Tr. 1204 (*in camera*)).

2347. [REDACTED] (Chudova (Guardant) Tr. 1154-55).

2348. [REDACTED] } (Chudova (Guardant) Tr. 1205-06 (*in camera*)).

2349. [REDACTED] } (Chudova (Guardant) Tr. 1205-06 (*in camera*)).

6. [REDACTED]

2350. [REDACTED] } (PX7105 (Getty (Guardant) Dep. at 131-35) (*in camera*)).

2351. [REDACTED] (Getty (Guardant) Tr. 2542 (*in camera*)).

2352. [REDACTED] (PX8305 (Guardant) at 062 (Guardant Health Q3 2020 BOD Meeting, Nov. 2020) (*in camera*)) ([REDACTED]); *see also* (PX7100 (Chudova (Guardant) Dep. at 27-28) (*in camera*)).

7. [REDACTED]  
[REDACTED]

**D. FREENOME IS DEVELOPING AN MCED TEST AS AN EXPANSION OF ITS COLORECTAL CANCER SCREENING TEST**

**1. Background**

2353. [REDACTED] } (PX7055 (Otte (Freenome) IHT at 14) (*in camera*)).

2354. Freenome was founded in 2014. (PX7121 (Otte (Freenome) Dep. at 13)).

**2. Freenome’s MCED Test Technological Platform Is Designed to Be Able to Host a Multi-Cancer Test**

2355. [REDACTED] (PX7050 (Nolan (Freenome) IHT at 43-44) (*in camera*); PX7121 (Otte (Freenome) Dep. at 17-19) (*in camera*)).

2356. [REDACTED] } (Nolan (Freenome) Tr. 2748-49 (*in camera*)).

2357. [REDACTED] (Nolan (Freenome) Tr. 2748-49 (*in camera*)).

2358. Freenome is developing cancer screening tests based on multiomics. (Nolan (Freenome) Tr. 2706).

2359. In general, multiomics describes a biological analysis approach that involves identifying and measuring “a range of analytes” such as DNA methylation, genomics, proteomics, and transcriptomics, among others. (Nolan (Freenome) Tr. 2710-11).

2360. [REDACTED] } (PX7121 (Otte (Freenome) Dep. at 29-31) (*in camera*); PX7055 (Otte (Freenome) IHT at 44-47) (*in camera*); PX4048 (Grail) at 013 [REDACTED] (*in camera*)).
2361. Freenome’s multiomics platform is designed to detect tumor-derived biological signatures and non-tumor derived biological signatures. (Nolan (Freenome) Tr. 2712).
2362. [REDACTED] (PX8368 (Freenome) at 005 (Crossover Round Company Overview, 2020) (*in camera*)).
- a) Freenome Will Launch a Colorectal Cancer Screening Test First Before Expanding to an MCED Test
2363. Freenome’s cancer screening test development has “start[ed] with [the] detection of colorectal cancer and advanced adenomas from a blood sample.” (Nolan (Freenome) Tr. 2706).
2364. [REDACTED] } (PX7055 (Otte (Freenome) IHT at 20-21) (*in camera*)).
2365. Freenome CEO, Michael Nolan testified at trial that “[Freenome] started [with a colorectal cancer screening test] because it is well-characterized. Physicians know when to order it. The reimbursement and medical policy frameworks are supportive in that the unmet need is very clear.” (Nolan (Freenome) Tr. 2708).
2366. Freenome expects that focusing initially on developing a colorectal cancer screening test will [REDACTED] } (Nolan (Freenome) Tr. 2760 (*in camera*)).
2367. [REDACTED] } (Nolan (Freenome) Tr. 2761 (*in camera*)).
2368. [REDACTED] } (Nolan (Freenome) Tr. 2762 (*in camera*); PX7050 (Nolan (Freenome) IHT at 72) (*in camera*)).
2369. [REDACTED] } (Nolan (Freenome) Tr. 2765 (*in camera*)).
2370. [REDACTED] } (Nolan (Freenome) Tr. 2748 (*in camera*)).



2371. [REDACTED]  
[REDACTED] (PX7094 (Nolan (Freenome) Dep. at 26-28) (*in camera*)).

2372. [REDACTED]  
[REDACTED] (PX7094 (Nolan (Freenome) Dep. at 26-27) (*in camera*)).

b) [REDACTED]  
[REDACTED]

2373. [REDACTED]  
[REDACTED] } (PX7121 (Otte (Freenome) Dep. at 17-18) (*in camera*)). At trial, Mr. Nolan testified that Freenome’s multiomics platform is “built for the purpose of having application across a range of cancer types[.]” (Nolan (Freenome) Tr. 2709).

2374. While developing its early detection colorectal cancer test, Freenome plans to “tak[e] a stepwise approach to get to other cancer types so that [Freenome] can deliver benefits of early detection across a range of different cancers.” (Nolan (Freenome) Tr. 2706).

2375. [REDACTED]  
[REDACTED] (Nolan (Freenome) Tr. 2751-52 (*in camera*)).

2376. [REDACTED]  
[REDACTED] } (Nolan (Freenome) Tr. 2709; *see also* (Nolan (Freenome) Tr. 2747-48 (*in camera*))).

2377. [REDACTED]  
[REDACTED] } (Nolan (Freenome) Tr. 2761 (*in camera*)). Freenome’s CEO testified that Freenome is then able to [REDACTED]  
[REDACTED] (Nolan (Freenome) Tr. 2761 (*in camera*)).

2378. [REDACTED]  
[REDACTED] (PX7121 (Otte (Freenome) Dep. at 22) (*in camera*)).

2379. Freenome has [REDACTED]  
[REDACTED] } (Nolan (Freenome) Tr. 2748-50 (*in camera*)).

2380. Freenome CEO Michael Nolan testified that [REDACTED] [REDACTED] } (Nolan (Freenome) Tr. 2749-50 (in camera)).

2381. Mr. Nolan explained at trial that the [REDACTED] [REDACTED] } (Nolan (Freenome) Tr. 2749 (in camera)).

2382. Mr. Nolan further testified that Freenome [REDACTED] [REDACTED] } (Nolan (Freenome) Tr. 2748 (in camera); see also Nolan (Freenome) Tr. 2766-67 (in camera)).

2383. [REDACTED] } (PX8368 (Freenome) at 014 (Crossover Round Company Overview, 2020) (in camera); see PX7121 (Otte (Freenome) Dep. at 168-69) (testifying that Freenome expects to launch a CRC screening test in 2022 and add additional cancers in 2023 and 2024)).

2384. Freenome CEO, Michael Nolan, testified that Freenome plans to [REDACTED] [REDACTED] } (Nolan (Freenome) Tr. 2751 (in camera)).

2385. [REDACTED] } (Nolan (Freenome) Tr. 2769 (in camera)). At trial, Freenome CEO, Michael Nolan, explained that Freenome is [REDACTED] [REDACTED] } (Nolan (Freenome) Tr. 2852-53 (in camera)).

2386. [REDACTED] } (Nolan (Freenome) Tr. 2772 (in camera)).

2387. At trial, Mr. Nolan explained that Freenome plans to start by offering its tests as an LDT out of its own laboratory. (Nolan (Freenome) Tr. 2706-07). Then, Freenome plans to “take a stepwise approach to add additional sites for operation resilience and also for very specific country-level access and then evolve from there” to offering its test as a distributed IVD test. (Nolan (Freenome) Tr. 2706-07).

2388. [REDACTED] } (Nolan (Freenome) Tr. 2772 (in camera)).

2389. [REDACTED] [REDACTED] } (Nolan (Freenome) Tr. 2769-70) (in camera)).

2390. [REDACTED] [REDACTED] } (Nolan (Freenome) Tr. 2748 (in camera)).

2391. Freenome's CEO testified that Freenome plans on [REDACTED] } (Nolan (Freenome) Tr. 2748 (*in camera*)).

2392. Freenome is also [REDACTED] (Nolan (Freenome) Tr. 2709; *see also* Nolan (Freenome) Tr. 2766 (*in camera*)).

3. [REDACTED]

2393. [REDACTED] } (PX7050 (Nolan (Freenome) IHT at 67-68, 72) (*in camera*)).

2394. [REDACTED] (PX7050 (Nolan (Freenome) IHT at 60-61)).

2395. [REDACTED] } (Nolan (Freenome) Tr. 2799 (*in camera*)).

2396. [REDACTED] (Nolan (Freenome) Tr. 2761-62 (*in camera*)).

2397. [REDACTED] } (PX7055 (Otte (Freenome) IHT at 91) (*in camera*)).

2398. [REDACTED] (PX8368 (Freenome) at 015 (Crossover Round Company Overview, 2020) (*in camera*)). } [REDACTED]



{ }

(PX8368 (Freenome) at 015 (Crossover Round Company Overview, 2020) (*in camera*)).

4. [Redacted]

2399. [Redacted] (PX7121 (Otte (Freenome) Dep. at 96) (*in camera*)).

2400. [Redacted] (PX7055 (Otte (Freenome) IHT at 16) (*in camera*)).

5. [Redacted]

See Complaint Counsel’s Proposed Findings of Fact Section VII.B.3.a.3.

**E. SINGLERA HAS ALREADY CONDUCTED A 100,000 SAMPLE TRIAL FOR ITS MCED TEST IN DEVELOPMENT—PANSEER**

**1. Background**

2401. Singlera is headquartered in Shanghai, China and has U.S. offices in La Jolla, California. (Gao (Singlera) Tr. 2870; PX7042 (Gao (Singlera) IHT at 21)).

2402. Singlera currently operates four laboratories. (Gao (Singlera) Tr. 2870).
2403. Dr. Gary Gao and Professor Kun Zhang cofounded Singlera Genomics in 2014. (Gao (Singlera) Tr. 2865, 2869; PX7042 (Gao (Singlera) IHT at 15)).
2404. Singlera is a test developer focused on early cancer detection using targeted DNA methylation technology for cell-free DNA. (Gao (Singlera) Tr. 2869-70).
2405. “Based on next-generation sequencing platform, Singlera is a world leader on tissue and cfDNA methylation sequencing with patented proprietary technologies. Singlera has developed a series of methods for early screening, early-stage diagnosis and prevention of cancers, including lung cancer, colorectal cancer, gastric cancer, liver cancer, and esophageal cancer.” (PX8517 (Singlera) at 001 (Company Overview)).
2406. Dr. Gao testified that Singlera’s “goal is to detect cancer early, all kinds of cancer.” (PX7042 (Gao (Singlera) IHT at 21)).
2407. Singlera ultimately has the “goal [] to improve health standards for all.” (PX8517 (Singlera) at 001 (Company Overview)).
2408. Illumina considers Singlera as a “[p]rovider of non-invasive oncology and reproductive health tests using single cell sequencing, DNA methylation, and machine learning technology.” (PX2780 (Illumina) at 001 (Singlera Genomics - Overview)).

## **2. Singlera’s Single-Cancer Screening Tests**

2409. Singlera is developing four single-cancer screening tests and one MCED test in the United States. (Gao (Singlera) Tr. 2873, 2914).
2410. Singlera is developing single-cancer early detection tests for colorectal cancer, lung cancer, pancreatic cancer, and throat cancer. (Gao (Singlera) Tr. 2873, 2914).
2411. Singlera’s single cancer tests for lung cancer, pancreatic cancer, and throat cancer use DNA methylation to detect cancer. (Gao (Singlera) Tr. 2914).
2412. Singlera’s ColonES test is a blood-based early detection test for colorectal cancer. (Gao (Singlera) Tr. 2873-74).
2413. ColonES uses DNA methylation to detect colorectal cancer. (Gao (Singlera) Tr. 2873-74).
2414. “ColonES is currently the only colorectal product that can detect early adenoma.” (PX8517 (Singlera) at 001 (Company Overview)). “Detecting early adenoma is necessary for preventing colorectal cancer (CRC)[.]” (PX8517 (Singlera) at 001 (Company Overview)).
2415. Singlera’s ColonES test is “the same targeted DNA methylation analysis” as used with its pan-cancer test, PanSeer. (Gao (Singlera) Tr. 2915).

2416. Dr. Gao explained that Singlera is starting with a colorectal cancer early detection test because “the complexity to get FDA approval and reimbursement is also much lower, so we use it as a kind of test case scenario.” (PX7042 (Gao (Singlera) IHT at 119-20)).

### 3. Singlera is Developing an MCED Test—PanSeer

2417. Singlera is currently developing an MCED test referred to as PanSeer. (PX7102 (Gao (Singlera) Dep. at 23-24)).

2418. Singlera’s PanSeer test is a blood-based early detection test designed to detect multiple cancers. (Gao (Singlera) Tr. 2876, 2881-82).

2419. Singlera has developed “PanSeer” technology, which in theory works for any type of cancer. (PX7102 (Gao (Singlera) Dep. at 94-95)).

2420. From a test development perspective, Dr. Gao explained that ColonES and PanSeer both use the same method for detecting cancer: “That’s the beauty of the methylation technology platform. It’s the same methylation analysis, assay and software and algorithm, but your target is different.” (PX7042 (Gao (Singlera) IHT at 117, 119-20)).

2421. Singlera’s PanSeer test is designed to detect all kinds of cancer, and not just the five cancers used in the Taizhou Longitudinal Study. (Gao (Singlera) Tr. 2881). Dr. Gao testified that Singlera’s “goal is pan-cancer” for the PanSeer test. (Gao (Singlera) Tr. 2881).

2422. PanSeer is the “[o]nly product in the [w]orld for multiple types of cancer early screening that was validated by healthy population studies.” (PX8517 (Singlera) at 001 (Company Overview)).

2423. The PanSeer test can detect lung cancer, liver cancer, colorectal cancer, esophageal cancer, and gastric cancer. (PX8517 (Singlera) at 001 (Company Overview)).

2424. PanSeer can detect lung cancer at a 93 percent sensitivity. (PX8517 (Singlera) at 001 (Company Overview)). PanSeer can detect liver cancer at a 94 percent sensitivity. (PX8517 (Singlera) at 001 (Company Overview)). PanSeer can detect colorectal cancer at 89 percent sensitivity. (PX8517 (Singlera) at 001 (Company Overview)). PanSeer can detect esophageal cancer at 89 percent sensitivity. (PX8517 (Singlera) at 001 (Company Overview)). PanSeer can detect gastric cancer at 70 percent sensitivity. (PX8517 (Singlera) at 001 (Company Overview)).

2425. PanSeer “detects cancer [four] years earlier than conventional diagnoses.” (PX8517 (Singlera) at 001 (Company Overview)).

2426. The PanSeer test is also designed to detect tissue of origin. (Gao (Singlera) Tr. 2874).

2427. The PanSeer test uses targeted DNA methylation technology to analyze over 500 regions on a DNA sample. (Gao (Singlera) Tr. 2874-75; *see* PX7042 (Gao (Singlera) IHT at 21) (testifying that Singlera’s “technology is based on analyzing DNA methylation pattern of cell-free ctDNA in the blood.”))

2428. PanSeer’s technology can detect many types of cancer using methylation patterns as biomarkers. (PX7102 (Gao (Singlera) Dep. at 22-24)).
2429. Dr. Gao testified that Singlera has spent between \$60 million to \$100 million on research and development efforts related to the PanSeer test. (Gao (Singlera) Tr. 2888-2889).
2430. While the PanSeer test is currently focused on screening for colorectal, lung, gastric, esophageal, and liver cancers, it may add more cancers prior to commercialization and could end up detecting “any kind of cancer.” (PX7042 (Gao (Singlera) IHT at 28-30); *see* Gao (Singlera) Tr. 2881).
2431. Dr. Gao testified that Singlera’s “goal is pan-cancer” for the PanSeer test. (Gao (Singlera) Tr. 2881).
2432. Singlera plans to seek FDA approval for its PanSeer Test. (Gao (Singlera) Tr. 2881).
2433. Singlera plans to further develop the PanSeer test design before seeking FDA approval. (Gao (Singlera) Tr. 2881).

a) Singlera Plans to Launch PanSeer Using a Distributed Model

2434. Singlera’s business model is to offer the PanSeer test as a distributed test in order to differentiate it from single-site tests. (PX7042 (Gao (Singlera) IHT at 109)).
2435. To turn the PanSeer test into a distributed model, Singlera must follow the “FDA clinical trial study protocol” which means running “at least three sites.” (PX7042 (Gao (Singlera) IHT at 109-10)).
2436. Singlera noted that the “[t]est will be sold to and performed at external CLIA labs,” “[u]nlimited number of labs can sell test assuming they have equipment and personnel,” “CLIA labs responsible for running assay, reporting results, billing patients, QC, QA, etc.” Singlera “must provide complete kits” meaning they “are responsible for kit manufacturing, QC, supply agreements, supply chain management[,] [and] upload[ing] software to Illumina’s cloud.” The FDA trial for a distributed test “must be performed in 3 CLIA labs.” (PX8518 (Singlera) at 009 (FDA Update: PMA vs 510k)).
2437. Dr. Gao testified that an advantage of offering a distributed IVD test is that “you can quickly convince partner – you know, LabCorp, Quest [] to quickly adopt your system instead of you building your capacity up, scale up, like Exact Sciences.” (PX7042 (Gao (Singlera) IHT at 110)).
2438. Dr. Gao testified that selling the PanSeer test as a distributed test would allow Singlera to “quickly scale up to sell.” (PX7042 (Gao (Singlera) IHT at 110-11); *see* PX8518 (Singlera) at 011 (FDA Update: PMA vs 510k)).
2439. Dr. Gao testified that the customers of a distributed IVD test would be the same as the customers of a single-site test because “the customer won’t care [about] your business model, [] they only care about result.” (PX7042 (Gao (Singlera) IHT at 111)).

2440. In order for a non-Singlera lab to run a Singlera test on an Illumina sequencer, Illumina must authorize the use of its sequencer. (PX7042 (Gao (Singlera) IHT at 112-13)).
2441. Dr. Gao testified that “a distributed model will have an advantage” for Singlera, and without a distributed model, Singlera would be at a competitive disadvantage to other pan-cancer screening companies that were authorized to sell a distributed IVD test. (PX7042 (Gao (Singlera) IHT at 114-15)).
- b) Singlera Hired Consulting Firm CSSi to Aid Its FDA and Commercial Development
2442. CSSi Life Sciences is a consulting company which helps its clients take a product from discovery to the clinical research and FDA review/approval stage of development. (See PX8656 (Singlera) at 002 (CSSi Life Sciences: Accelerating Discovery to Commercialization)).
2443. Singlera contracted with CSSi in February 2019 for “regulatory, preclinical, CMC, clinical, CRO, and/or other services” relating to Singlera’s “blood-based colon cancer in vitro diagnostic (IVD) that uses Next Generation Sequencing (NGS) for methylation haplotype analysis of cell-free DNA.” (PX8657 (Singlera) at 001, 013 (CSSi Life Sciences Service Agreement, Feb. 1, 2019)).
2444. Singlera hired CSSi because Singlera is “a small company [and] do[es] not have the expertise to go through [the] FDA [alone] for the first time.” (PX7102 (Gao (Singlera) Dep. at 41)).
2445. CSSi helps reduce a product’s “[t]ime to market and development costs” and “[r]isk for late-stage failures and post authorization action” while increasing “[c]ommercial success and early adoption” and “[s]takeholder value and return.” (PX8656 (Singlera) at 004 (CSSi Life Sciences: Accelerating Discovery to Commercialization)).
2446. Dr. Gao testified that CSSi was “very expensive” to use. (PX7102 (Gao (Singlera) Dep. at 41)). The hourly rate for CSSi’s regulatory and clinical strategy personnel was \$400. (PX8657 (Singlera) at 016 (CSSi Life Sciences Service Agreement, Feb. 1, 2019)).
2447. CSSi “basically tell[s] [Singlera] what needs to be done, prepare documents, [] call a meeting with the FDA. So they are more like [a] consultancy.” (PX7102 (Gao (Singlera) Dep. at 41)). In other words, CSSi walked Singlera through the FDA regulatory approval process. (PX7102 (Gao (Singlera) Dep. at 41-42) (“Q. Okay. So CSSi can walk the company like Singlera through the FDA regulatory approval process. Is that – did I understand that correctly? A. Yes. They are more hand-h[o]lding us through the jungle of regulatory, you know. So they will help out to coordinate study center, write up the plan, and communicate with FDA doing statistics. So that we call CIO.”)).
2448. As part of CSSi’s “health authority interactions” services they assist a company with “FDA/EMA Advisory Committee and Panel preparation,” “[o]ral explanation preparation,” “[m]ilestone meetings,” “[h]ealth authority responses to questions,” “[r]esolution and response to safety issues,” and “[r]epresentation with FDA and National



Competent Authorities.” (PX8656 (Singlera) at 018 (CSSi Life Sciences: Accelerating Discovery to Commercialization)).

2449. Dr. Gao explained that Singlera did not need to have its own in-house FDA expertise to go through the FDA regulatory process. Singlera instead hired CSSi. (PX7102 (Gao (Singlera) Dep. at 42)).

#### **4. Singlera’s PanSeer Completed a 100,000 Sample Clinical Trial**

2450. Singlera completed a proof-of-concept study of its PanSeer test in China on 100,000 people, identifying lung, esophageal, liver, colorectal, and gastric cancers at least four years before conventional diagnosis. (PX7042 (Gao (Singlera) IHT at 28-30)).

2451. Singlera’s PanSeer clinical study was called the Taizhou Longitudinal study. (Gao (Singlera) Tr. 2877-78).

2452. Singlera’s PanSeer test detected a total of five different types of cancers four years before participants showed symptoms in the Taizhou study. (Gao (Singlera) Tr. 2878-79).

2453. The PanSeer test demonstrated the ability to detect stomach cancer, esophageal cancer, liver cancer, colorectal cancer, and lung cancer in the Taizhou study. (Gao (Singlera) Tr. 2884).

2454. The Taizhou study demonstrated the PanSeer test has a sensitivity of “88 to 90 percent and [a] specificity of 96 percent” for the cancers used in the study. (Gao (Singlera) Tr. 2876).

2455. Singlera’s Taizhou study took place in Taizhou, China. (Gao (Singlera) Tr. 2878).

2456. Singlera’s Taizhou study involved 123,115 participants. (RX2717 (Singlera) at 001 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).

2457. “In the Taizhou Longitudinal Study (TZL), 123,115 healthy subjects provided plasma samples for long-term storage and were then monitored for cancer occurrence.” (RX2717 (Singlera) at 001 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).

2458. Singlera published the results of the Taizhou study in the peer-reviewed Nature Communications Journal in 2020. (Gao (Singlera) Tr. 2879-80).

2459. At trial, Dr. Gao also explained that all data associated with the Taizhou study, including “all the original sequencing data [and] design data[,]” were made publicly available “so any statistician, biologist, any computer scientist can download, analyze themselves, to see if the results we published agree with the data.” (Gao (Singlera) Tr. 2880).

2460. The Nature article reported “the preliminary results of PanSeer, a noninvasive blood test based on circulating tumor DNA methylation, on TZL plasma samples from 605 asymptomatic individuals, 191 of whom were later diagnosed with stomach, esophageal,

- colorectal, lung or liver cancer within four years of blood draw.” (RX2717 (Singlera) at 001 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).
2461. The five cancer types studied in Taizhou “account for 261,530 yearly cancer deaths in the US and 2.1 million yearly cancer deaths in China; early detection could greatly reduce deaths from these diseases.” (RX2717 (Singlera) at 007 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).
2462. “The PanSeer assay was able to successfully detect five cancer types using a common set of methylation markers regardless of tissue-of-origin. As such, the genes included in the LR classifier represent a core epigenetic signature common to multiple cancer types.” (RX2717 (Singlera) at 005 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).
2463. The PanSeer “assay is most likely identifying patients who already have cancerous growths but who remain asymptomatic to current detection methods and standard of care, as many cancers do not cause the appearance of symptoms until late in disease development.” (RX2717 (Singlera) at 006 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).
2464. “The PanSeer assay was solely developed to detect cancer regardless of the tissue-of-origin by targeting a limited number of genomic regions that are commonly aberrantly methylated across different cancer types, allowing it to be used as a potential first-line inexpensive cancer screen; it also requires a comparatively small amount of input DNA (from only a single tube of blood).” (RX2717 (Singlera) at 006 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).
2465. “The PanSeer assay provides a preliminary demonstration of early detection of multiple cancer types four years prior to conventional diagnosis in a robust manner, and lays the foundation for a non-invasive blood test for early detection of cancer in a high-risk (or average-risk in the future) population.” (RX2717 (Singlera) at 006-007 (Non-invasive early detection of cancer four years before conventional diagnosis using a blood test, July 21, 2020)).
2466. Dr. Gao testified at trial that Singlera has received recognition from industry publications for its PanSeer test after publishing the results of the Taizhou study. (Gao (Singlera) Tr. 2880).
2467. Singlera plans to showcase the PanSeer test’s ability to detect more cancers than the five demonstrated in the Taizhou study. (Gao (Singlera) Tr. 2881-82).
2468. Dr. Gao testified at trial that demonstrating the ability to detect additional cancers will require a prospective study. (Gao (Singlera) Tr. 2881).
2469. Singlera hopes to start its FDA trial for PanSeer in two to three years. (PX7042 (Gao (Singlera) IHT at 96)).

2470. Dr. Gao testified at trial that the study designs for the clinical studies conducted using Grail’s Galleri test and PanSeer are different. (Gao (Singlera) Tr. 2885).
2471. At trial, Dr. Gao explained that Grail conducted a case control study on individuals already diagnosed with cancer, but Singlera conducted its Taizhou study on asymptomatic individuals. (Gao (Singlera) Tr. 2885-87).

**5. Singlera Has Invested Approximately \$250 Million on PanSeer’s Development**

2472. Singlera has raised over \$250 million from investors to date, including a \$150M fundraising round in 2020. (PX7042 (Gao (Singlera) IHT at 22-24)).
2473. Dr. Gao testified that Singlera has spent between \$60 million to \$100 million on research and development efforts related to the PanSeer test. (Gao (Singlera) Tr. 2888-2889).
2474. Singlera is working to “reduce cost, improve accuracy, and improve convenience” of its test. (PX7042 (Gao (Singlera) IHT at 100)).

**6. Singlera Expects to Launch PanSeer in the U.S. in 2028 and Will Not Offer PanSeer as an LDT in the U.S.**

2475. Singlera expects to launch PanSeer in the United States around 2028 as an FDA approved test. (PX7042 (Gao (Singlera) IHT at 96)).
2476. Dr. Gao testified that it is “very possible [Singlera] will be able to market [the] PanSeer” test in the Chinese market as an LDT “in the next . . . two to three years.” (Gao (Singlera) Tr. 2892).
2477. Dr. Gao testified that he is not aware of any path under which the FDA would allow Singlera to market the “PanSeer in the U.S. without FDA approval.” (Gao (Singlera) Tr. 2892).

**7. Singlera and Grail Consider One Another Competitors in MCED**

See Complaint Counsel’s Proposed Findings of Fact Section VII.B.3.a.4.

**F. HELIO HEALTH IS DEVELOPING ITS MCED TEST ON THE SAME PLATFORM AS ITS HELIOLIVER TEST**

**1. Background**

2478. Helio Health, Inc. (“Helio”) is a healthcare company focused on the early detection of cancer using blood specimens. (Chahine (Helio) Tr. 1000; PX7077 (Chahine (Helio) Dep. at 12)).
2479. Helio previously operated under the name Laboratory for Advanced Medicine (“LAM”). (Chahine (Helio) Tr. 1001-02).

2480. [REDACTED] } (PX8655 (Helio) at 006 [REDACTED] (*in camera*)).

2481. [REDACTED] (Chahine (Helio) Tr. 1058-59 (*in camera*)).

2482. Dr. Chahine, Helio’s former CEO, testified that Helio is “probably one of the earlier companies in the category.” (Chahine (Helio) Tr. 1001).

2483. Helio has operations in the United States and China. (Chahine (Helio) Tr. 1025).

2484. [REDACTED] } (PX8655 (Helio) at 019, 045 [REDACTED] (*in camera*)).

**2. HelioLiver Test**

2485. [REDACTED] (Chahine (Helio) Tr. 1000-01, 1009-10; PX7077 (Chahine (Helio) Dep. 15-17) (*in camera*)).

2486. When still operating as LAM, Helio used the name “IvyGene” for the liver cancer screening test now known as HelioLiver. (Chahine (Helio) Tr. 1001-02).

2487. [REDACTED] } (Chahine (Helio) Tr. 1010-11; 1057-58 (*in camera*)); PX7077 (Chahine (Helio) Dep. at 15-16) (*in camera*)).

2488. [REDACTED] (Chahine (Helio) Tr. 1069 (*in camera*)).

2489. Helio currently performs the sequencing for the HelioLiver test at its own certified lab as well as third-party labs. (Chahine (Helio) Tr. 1011-12).

2490. Helio chose to develop a liver cancer screening test because of the large market opportunity in the United States and China, which has the largest number of liver cancer cases in the world. (Chahine (Helio) Tr. 1025).

2491. [REDACTED] } (PX6049 (Grail) at 038 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

2492. [REDACTED] } (PX7077 (Chahine (Helio) Dep. at 16-17) (*in camera*); Chahine (Helio) Tr. 1050 (*in camera*)).

2493. [REDACTED] (Chahine (Helio) Tr. 1050 (*in camera*)).

a) [REDACTED]

2494. [REDACTED] (Chahine (Helio) Tr. 1064-65 (*in camera*)).

2495. [REDACTED] } (Chahine (Helio) Tr. 1065-66 (*in camera*)).

2496. [REDACTED] (Chahine (Helio) Tr. 1066 (*in camera*)).

2497. [REDACTED] (Chahine (Helio) Tr. 1064-65 (*in camera*)).

2498. [REDACTED] (Chahine (Helio) Tr. 1050-51 (*in camera*)).

2499. [REDACTED] } (Chahine (Helio) Tr. 1051-52 (*in camera*)).

2500. [REDACTED] } (Chahine (Helio) Tr. 1052 (*in camera*)).

**3. Helio Is Developing an MCED Test on the HelioLiver Technological Platform**

2501. [REDACTED] (Chahine (Helio) Tr. 1057 (*in camera*)).

2502. Helio is researching additional cancers to add to the HelioLiver test platform. (Chahine (Helio) Tr. 1039).

2503. [REDACTED] } (Chahine (Helio) Tr. 1000-01). (PX8655 (Helio) at 019 [REDACTED] (*in camera*)).

2504. [REDACTED] (Chahine (Helio) Tr. 1056-57 (*in camera*)).

2505. [REDACTED] } (Chahine (Helio) Tr. 1056-57 (*in camera*)).

2506. [REDACTED] } (Chahine (Helio) Tr. 1056-57 (*in camera*)).

2507. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 33-34 (*in camera*))).

2508. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 34 (*in camera*))).

2509. [REDACTED] (Chahine (Helio) Tr. 1058-59 (*in camera*)).

2510. [REDACTED] } (Chahine (Helio) Tr. 1057-58 (*in camera*)).

2511. When considering which cancers to add to HelioLiver, Helio has prioritized by reviewing the research conducted on other cancer types and the cost to conduct a clinical trial for each cancer. (Chahine (Helio) Tr. 1039-40). Helio also considers the prevalence of a cancer and the corresponding market size for a test that detects that cancer when considering what cancers to add to its screening test. (Chahine (Helio) Tr. 1040-41). In addition, Helio considers the lethality of a cancer when considering what cancers to add to its cancer screening test. (Chahine (Helio) Tr. 1041).

2512. [REDACTED] } (PX7077 (Chahine (Helio) Dep. at 15); PX8655 (Helio) at 013 [REDACTED] (*in camera*)).

2513. [REDACTED] } (PX8655 (Helio) at 027 [REDACTED] (*in camera*)).

2514. Helio told its investors that Helio intends to develop an MCED test by adding additional cancers to its single-cancer HelioLiver test. (Chahine (Helio) Tr. 1037).

2515. Per Dr. Chahine, Helio has not set a limit on the number of cancers it plans to include in its MCED test. (Chahine (Helio) Tr. 1043).

2516. [REDACTED] } (Chahine (Helio) Tr. 1069-70 (*in camera*)).

2517. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 15-16 (*in camera*))).

2518. [REDACTED] (Chahine (Helio) Tr. 1058 (*in camera*)).

2519. [REDACTED] (PX8655 (Helio) [REDACTED] (*in camera*)). } (See PX8655 (Helio) at 045 [REDACTED] ( [REDACTED] } (*in camera*)).

2520. [REDACTED] (PX8655 (Helio) at 013 [REDACTED] (*in camera*)).

2521. [REDACTED] (PX8655 (Helio) at 019 [REDACTED] (*in camera*)).

2522. [REDACTED] (PX8655 (Helio) at 024 [REDACTED] (*in camera*)).

2523. [REDACTED] } (RX0894 (Helio) at 015, 022 (Helio Health, May 31, 2021) (*in camera*)).

2524. [REDACTED] } (PX8655 [REDACTED])

(Helio) at 018 [REDACTED] (in camera).

2525. [REDACTED] } (RX0894 (Helio) at 25 (Helio Health, May 31, 2021) (in camera)).

2526. [REDACTED] } (PX8655 (Helio) at 028 (in camera)).

2527. [REDACTED] } (RX0894 (Helio) at 19 (Helio Health, May 31, 2021) (in camera)).

2528. [REDACTED] (PX8655 (Helio) at 038 (in camera)).

2529. [REDACTED] } (PX8655 (Helio) at 031 (in camera)). (PX8655 (Helio) at 038 (Email from D. Taggart, Helio, to M. Gallant, Helio, attaching LAM Company and Technology Overview, Mar. 7, 2019) (in camera)).

2530. [REDACTED] } (PX8655 (Helio) at 039 (in camera)).

a) [REDACTED]

2531. [REDACTED] (Chahine (Helio) Tr. 1061-62 (in camera)).

2532. [REDACTED] (Chahine (Helio) Tr. 1061-63 (in camera)).

2533. [REDACTED]



[REDACTED] } (PX8655 (Helio) at 008  
[REDACTED] (*in camera*)).

2534. [REDACTED]  
[REDACTED] (Chahine (Helio) Tr. 999, 1061 (*in camera*)).

2535. [REDACTED] } (PX8655 (Helio) at 031  
[REDACTED] (*in camera*)).  
[REDACTED] (PX8655 (Helio) at 031  
[REDACTED] (*in camera*)).

2536. [REDACTED] } (Chahine (Helio) Tr.  
1061-62 (*in camera*)).

2537. [REDACTED] } (Chahine  
(Helio) Tr. 1062 (*in camera*)).

2538. [REDACTED] } (Chahine (Helio) Tr. 1062-63 (*in  
camera*)).

b) Helio’s Definition of “Cancer Type” Is Narrower Than the One  
Grail Uses When Grail Claims It Can Detect 50 Cancers

2539. [REDACTED] } (PX8655 (Helio) at 031  
[REDACTED] (*in camera*)).

2540. Dr. Chahine testified at trial that “broadly in the category” people define cancer types based on the organ where the cancer is located but it’s “far more complicated than that” because

“even within a certain organ you could have different cancer types and even different algorithms that would identify a certain cancer type or not.” (Chahine (Helio) Tr. 1042).

2541. Grail uses the American Joint Committee on Cancer’s definition of cancer types. (RX2770 (2021 ASCO CCGA Poster)).

2542. [REDACTED] (PX8655 (Helio) at 031) (in camera)); RX2770 (2021 ASCO CCGA Poster); see infra Section X, Appendix B (Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population)).

**4. HelioLiver Is Undergoing an FDA Clinical Trial Now**

2543. Helio is conducting one clinical trial on its HelioLiver test, which is available on ClinicalTrials.gov. (Chahine (Helio) Tr. 1031).

2544. [REDACTED] (PX7077 (Chahine (Helio) Depo at 16-17, 20) (in camera)).

2545. Helio is currently in the last phase of clinical development for its HelioLiver test with the FDA. (Chahine (Helio) Tr. 1020).

**5. [REDACTED]**

2546. Dr. Chahine testified at trial that the R&D process to develop a screening test is “extremely expensive,” and the two major costs are “acquiring actual samples” to conduct the analysis and the sequencing the samples. (Chahine (Helio) Tr. 1035-36).

2547. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 28-29) (in camera)).

2548. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 40-41) (in camera)) ( [REDACTED] ).

2549. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 33-34) (in camera)).

6. [REDACTED]

2550. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 16-17) (in camera)).

2551. [REDACTED] (PX7077 (Chahine (Helio) Dep. at 31) (in camera)).

2552. [REDACTED] (Chahine (Helio) Tr. 1061 (in camera)).

2553. [REDACTED] (Chahine (Helio) Tr. 1062-63 (in camera)).

2554. [REDACTED] (Chahine (Helio) Tr. 1063 (in camera)).

2555. [REDACTED] (Chahine (Helio) Tr. 1063 (in camera)).

2556. [REDACTED] (Chahine (Helio) Tr. 1061-62 (in camera)).

7. [REDACTED]

[REDACTED]

G. [REDACTED]

1. [REDACTED]

2557. [REDACTED]

2558. [REDACTED]

2559. [REDACTED]

2560. [REDACTED]

2561. [REDACTED]

2. [REDACTED]

2562. [REDACTED]

2563. [REDACTED]

2564. [REDACTED]

2565. [REDACTED]

2566. [REDACTED]

2567. [REDACTED]

2568. [REDACTED]

[REDACTED]

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[REDACTED]

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[REDACTED]

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[REDACTED]

2575.

[REDACTED]

2576.

[REDACTED]

3.

[REDACTED]

2577.

[REDACTED]

2578.

[REDACTED]

2579. [REDACTED]

2580. [REDACTED]

2581. [REDACTED]

2582. [REDACTED]

2583. [REDACTED]

2584. [REDACTED]

2585. [REDACTED]

2586. [REDACTED]

2587. [REDACTED]

2588. [REDACTED]

2589. [REDACTED]

2590. [REDACTED]

2591. [REDACTED]

4. [REDACTED]

2592. [REDACTED]

2593. [REDACTED]

2594. [REDACTED]

5. [REDACTED]

[REDACTED]

**H. OTHER MCED TEST DEVELOPERS**

1. [REDACTED]

2595. [REDACTED]

2596. [REDACTED]

2597. [REDACTED]

2598. [REDACTED]

2599. [REDACTED] (PX4139 (Grail) at 002, 005 (Email from A. Tosti, Grail, to E. Mann, Grail, May 28, 2020, attaching press release, “2019 AACR Breakthrough in Application of Methylation Ultra-deep Sequencing in Liquid Biopsy for Early Lung Cancer Screening,” Aug. 26, 2019).

2600. [REDACTED] (PX2163 (Illumina) at 008 (in camera)).

2601. [REDACTED] (PX7085 (Harada (Exact) Dep. at 76, 227) (in camera)).

2602. [REDACTED]

2. [REDACTED]

2603. [REDACTED] (PX7050 (Nolan (Freenome) IHT at 280-82) (in camera); PX7089 (Naclerio (Illumina) Dep. at 16); PX7094 (Nolan (Freenome) Dep. at 261) (in camera)).

2604. [REDACTED] (PX7050 (Nolan (Freenome) IHT at 280-82) (in camera)).

2605. [REDACTED] (PX7094 (Nolan (Freenome) Dep. at 261) (in camera)).

3. [REDACTED]

2606. [REDACTED]

**VII. THE PROPOSED MERGER WILL SUBSTANTIALLY LESSEN COMPETITION IN THE U.S. MCED TEST MARKET**

**A. ILLUMINA HAS THE ABILITY TO HARM GRAIL’S RIVALS**

2607. As discussed in detail above in Section V., MCED test developers testified that they have no viable alternatives and that they need and rely on Illumina as their only NGS option.



**1. Illumina Has the Ability to Identify and Discriminate Against MCED Test Developers Posing Competitive Threats to Grail’s Galleri Test and the Tools to Foreclose or Reduce the Competitiveness of Grails’ Rivals**

a) Illumina Designs and Offers Products Tailored for Customers to Use in Certain Applications, Including Providing Custom Kits Not Just for Specific Applications but Also for Specific Customers

2608. Nicole Berry, Illumina’s Senior Vice President and General Manager of the Americas Commercial Region, testified that Illumina classifies customers based on segments such as reproductive health, genetic disease testing, and oncology on the clinical side, and cell and molecular biology research, genetic disease research, cancer research, and microbiology on the research side. (PX7076 (Berry (Illumina) Dep. at 54-57); *see infra* Complaint Counsel’s Proposed Findings of Fact ¶¶ 2694-2701 (identifying Illumina oncology customers as part of Illumina’s post-transaction announcement outreach)).

2609. [REDACTED] } (Berry (Illumina) Tr. 792-793) (*in camera*). For example, Ms. Berry testified that [REDACTED] } (Berry (Illumina) Tr. 795) (*in camera*)).

2610. [REDACTED] (Berry (Illumina) Tr. 795) (*in camera*)).

2611. Ms. Berry explained that Illumina offers “12 to 15 different kit configurations” for its NovaSeq sequencing instrument, so that it offers enough variety in reagents for “performance attributes that may be important to a particular customer.” (Berry (Illumina) Tr. 827).

2612. Customers will provide Illumina with details on their tests so that Illumina can recommend which of its consumables the customers should purchase. (*See* PX7076 (Berry (Illumina) Dep. at 62-64)).

2613. Ms. Berry admitted at trial that Illumina sells custom library kits to its NGS sequencing customers. (Berry (Illumina) Tr. 928 (stating that Illumina “sell[s] some very specific SKUs that . . . are absolutely marketed and designed for customers to, you know, specify their own specific content that they want to interrogate” and that “we [Illumina] will make a product specific to a customer’s request”)).

2614. Guardant’s Mr. Getty testified that Illumina provides Guardant with “customization and optimization of our reagents.” (PX7105 (Getty (Guardant) Dep. at 60-62)).

2615. [REDACTED] (PX2541 (Illumina) at 008 (Illumina, Interim Review K2-Grail (aka Grail “Pendragon”), Feb. 2, 2017) (*in camera*); *see infra* Section VII.D.3. (While Illumina Had Majority-Ownership, Grail Received Preferential Treatment)).

(1) Illumina Has the Tools to Identify Customers That Develop MGED Tests Likely to Compete with Grail’s Galleri Test

(a) *Illumina Has a Variety of Means and Sources to Access Information about Its Customers’ Products and Activities*

(i) *Illumina Learns about Its Customers’ Products and Development Plans from Conversations with Its Customers*

2616. Ms. Berry admitted at trial that Illumina identifies many customers that are buying its products for the purpose of developing or performing oncology tests through sales and service interactions with customers. (Berry (Illumina) Tr. 657-58).

2617. Ms. Berry explained that customers provide details about their tests to Illumina so that Illumina can recommend the appropriate consumables that they should purchase from Illumina. (PX7076 (Berry (Illumina) Dep. at 62-64)).

2618. Ms. Berry described how customers may inform Illumina’s sales team of their desired read length, analytes that they are detecting, and what platform they are using, among other things, to get input on which Illumina consumables meet their requirements. (PX7076 (Berry (Illumina) Dep. at 62-64)).

2619. Ms. Berry testified that sometimes when troubleshooting sequencing problems for a customer, a customer will provide Illumina with context about what they are using the sequencer for. (PX7076 (Berry (Illumina) Dep. at 32-35)).

2620. Illumina can learn information about tests from sources other than the test developer itself, such as lab customers, which can provide Illumina with information about the tests that lab customers are running. (See PX7049 (Bailey (PGDx) IHT at 175-76) (explaining that PGDx’s lab customers buy NGS products directly from Illumina, and testifying, “I do know examples of where [lab customers] have provided [the specific test] information. And because there is a lack of IVD kits on the market outside of ours it is not hard to figure out. I mean, if they need the Dx reagents there is nothing else right now really that would require that so I think it’s sort of understood when they are ordering those.”)).

2621. [REDACTED]  
[REDACTED] (PX7056 (Silvis (Tempus) IHT at 91-94) (*in camera*)).  
[REDACTED] } (PX7056 (Silvis (Tempus) IHT at 91-94) (*in camera*)).

2622. [REDACTED]

[REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 134-35) (*in camera*)).

2623. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 136-38) (*in camera*)).

2624. [REDACTED] } (PX7085 (Harada (Exact) Dep. at 218) (*in camera*)).

2625. Mr. Getty testified that Guardant works with Illumina to optimize Illumina reagents for the applications Guardant is using the reagents for. (PX7040 (Getty (Guardant) IHT at 59-61)).

2626. As Illumina CEO Mr. deSouza told investors, Illumina works with their liquid biopsy customers to help plan the customers’ “path to a regulated [product] offering.” (PX2544 (Illumina) at 019 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching JPM Life Sciences CEO Conference Call Transcript, Sept. 5, 2019)).

2627. Illumina CEO Mr. deSouza explained to investors that Illumina made structural changes to its operations to facilitate Illumina’s ability to “catalyze [] clinical opportunity” for its customers. (PX2544 (Illumina) at 019-020 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching JPM Life Sciences CEO Conference Call Transcript, Sept. 5, 2019)). Mr. deSouza remarked during his investor call discussion with JP Morgan’s Tycho Peterson that the Illumina clinical group has “no commercial components” but rather is designed to assist Illumina customers’ “clinical enablement.” (PX2544 (Illumina) at 020 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching JPM Life Sciences CEO Conference Call Transcript, Sept. 5, 2019)). Illumina’s clinical group works with Illumina’s clinical affairs, medical affairs, and regulatory teams. (PX2544 (Illumina) at 021 (Email from T. Peterson, JP Morgan, to F. deSouza, Illumina, attaching JPM Life Sciences CEO Conference Call Transcript, Sept. 5, 2019)).

(ii) *When Illumina Negotiates Supply Agreements and Offers Prices to Customers, It Examines Customers’ Applications, Industry Segments, and Product Developments*

2628. Nicole Berry testified at trial that Illumina typically “talk[s] to the customer about the various performance attributes that . . . our general-purpose reagents have . . . or our sequencing instruments have, and . . . that conversation could lead to an outcome whereby

a particular instrument platform or sequencing kit could be identified as likely to be best suited to their needs.” (Berry (Illumina) Tr. 658).

2629. In her deposition, Ms. Berry testified that Illumina learns of customers’ goals from supply agreement negotiations. (PX7076 (Berry (Illumina) Dep. at 52-55)).

2630. [REDACTED] } (PX7060 (Naclerio (Illumina) IHT at 126-27) (*in camera*)).

2631. Dr. Naclerio testified that Illumina has included “field of use” restrictions in its supply agreements to “reserve the right to charge a higher test fee” in future markets that may develop with tests that “would be priced at a much higher price.” (PX7060 (Naclerio (Illumina) IHT at 137)).

2632. [REDACTED] } (PX7057 (Flatley (Illumina) IHT at 95) (*in camera*); PX2241 (Illumina) at 001 [REDACTED])

2633. [REDACTED] } (PX7060 (Naclerio (Illumina) IHT at 119-20, 186) (*in camera*)).

2634. [REDACTED] } (PX7060 (Naclerio (Illumina) IHT at 121) (*in camera*)).

2635. During supply agreement negotiations with [REDACTED] } (See PX7076 (Berry (Illumina) Dep. at 258-66) (*in camera*); PX2301 (Illumina) at 001 [REDACTED] (*in camera*)).

2636. [REDACTED] (Berry (Illumina) Tr. 771-73) (*in camera*)).

2637. [REDACTED] } (PX8387 (Exact) at 001 [REDACTED] (*in camera*)).

2638. [REDACTED] (PX7058 (Conroy (Exact) IHT at 229-30) (*in camera*)).

2639. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(PX7076 (Berry (Illumina) Dep. at 260-61) (*in camera*)).

2640. Singlera’s Dr. Gao explained that Singlera had to tell Illumina about its PanSeer test while negotiating a contract: “We – in order to do this negotiation [with Illumina], we had to tell them what we are using it for, so they understand the customer need.” (PX7042 (Gao (Singlera) IHT at 81)).

2641. Singlera’s Dr. Gao explained that as part of supply agreement negotiations, Singlera told Illumina that Singlera planned to seek FDA approval for its ColonES test. (PX7042 (Gao (Singlera) IHT at 81-82)).

2642. Singlera’s Dr. Gao testified that in supply agreement negotiations with Illumina, Illumina proposed different fees for Singlera’s different uses of Illumina sequencers. For example, Illumina proposed a cap of \$4 million in market access fees relating to colorectal cancer tests, but a cap of \$10 million in market access fees relating to pan-cancer testing. (PX7042 (Gao (Singlera) IHT at 78-80)).

2643. [REDACTED]

[REDACTED]

(PX7040 (Getty (Guardant) IHT at 88-89) (*in camera*)).

2644. Mr. Getty testified that if Guardant were to order 10 new sequencers from Illumina, it would give Illumina a “very clear perspective[] that [Guardant was] expanding [its] business.” (PX7105 (Getty (Guardant) Dep. at 97-99)).

2645. Invitae’s CEO Sean George testified that Illumina seeks different prices for its products depending on what Invitae intends to use Illumina’s sequencers for. (PX7046 (George (Invitae) IHT at 67-73, 121)).

2646. Invitae’s Megan Bailey testified that Illumina requires Invitae to provide information on its development plans to Illumina as part of Invitae’s IVD agreement, including “the scope

of [Invitae's] studies, . . . the number of samples, what data parameters [Invitae] will look at, [and] some aspects of the study protocols needed to validate the kit." (PX7049 (Bailey (Invitae) IHT at 130-31)).

2647. Invitae's Megan Bailey testified that revenue share reporting requirements in Invitae's IVD agreement with Illumina could provide Illumina the opportunity to extrapolate Invitae's pricing strategy. (PX7049 (Bailey (Invitae) IHT at 132-33)).
2648. Kenneth Chahine, former Ancestry Executive VP, testified that when Ancestry sought to launch a health business, it informed Illumina of the change and requested to have Illumina perform NGS processing on Ancestry's health-related samples, similar to the way Illumina already processed Ancestry's genealogy samples on microarrays. (PX7077 (Chahine (Helio) Dep. at 72)). Illumina refused to process Ancestry's health-related samples on NGS because of a conflict with Illumina's relationship with another company, Helix. (PX7077 (Chahine (Helio) Dep. at 72-74)).

*(iii) Illumina Learns about Its Customers' Products and Development Plans from Public Information*

2649. Ken Song, former CEO of Ariosa Diagnostics, testified that Ariosa provided Illumina with "a fair amount of detail" regarding Ariosa's operations, in part because Illumina was an "important strategic supplier" for Ariosa's NIPT business. (PX7071 (Song (Omniome) IHT at 65)). During meetings where Ariosa provided Illumina with "confidential update[s] on [Ariosa's] progress, what [Ariosa] thought about putting in the tests, the cost structure, launch plans, [and] future product development plans," the Illumina personnel responsible for negotiating Ariosa's supply agreement were present. (PX7071 (Song (Omniome) IHT at 71-72)).
2650. Dr. Song testified that during negotiations relating to Ariosa's supply agreement with Illumina, Ariosa and Illumina discussed the specific allowable uses of Ariosa's NIPT offerings. (PX7071 (Song (Omniome) IHT at 73-77)).
2651. Ms. Berry testified that Illumina learns of customers' activities from customers' public disclosures. (PX7076 (Berry (Illumina) Dep. at 54-55, 57-58)).
2652. Illumina identifies many of its customers that are buying its products for the purpose of developing or performing oncology tests through public information. (Berry (Illumina) Tr. 655-56). For example, Illumina reviews company websites and regulatory filings to gather this information. (Berry (Illumina) Tr. 655-56).
2653. Ms. Berry testified that she's aware of which companies purchase Illumina products for use with oncology tests based on public information as well as her interactions with customers. (PX7063 (Berry (Illumina) IHT at 34-35)).
2654. Illumina CEO Francis deSouza testified at trial that Illumina tracks investment activity in MCED testing companies. (deSouza (Illumina) Tr. 2392).

2655. [REDACTED] (deSouza (Illumina) Tr. 2429; PX7072 (deSouza (Illumina) IHT at 243-44) (*in camera*)).

2656. [REDACTED] } (PX7072 (deSouza (Illumina) IHT at 125-26) (*in camera*)).

2657. [REDACTED] (PX7059 (Scagnetti (Illumina) IHT at 70-71) (*in camera*); PX5030 (Illumina) at 012 [REDACTED] (*in camera*)).

2658. [REDACTED] (PX7050 (Nolan (Freenome) IHT at 293-295) (*in camera*)).

2659. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 92-93) (*in camera*)).

2660. [REDACTED]

(2) Illumina Has Tools to Track How Customers Use Illumina NGS Products and for What Downstream Product

(a) *Illumina Learns about Its Customers' Products and Development Plans from Customers' Purchase History*

2661. [REDACTED] (PX6056 (Illumina) at 050 [REDACTED])

2662. [REDACTED] } (PX6056 (Illumina) at 050 [REDACTED])

2663. Ms. Berry testified that Illumina can learn customers' end uses from their purchase history. (PX7076 (Berry (Illumina) Dep. at 54-57)).

2664. Illumina is able to learn its customers' end uses from purchase history because certain Illumina consumables are better suited for certain applications. (PX7076 (Berry (Illumina) Dep. at 54-57); PX7063 (Berry (Illumina) IHT at 220-221)).

2665. Ms. Berry testified that Illumina's relationships with its customers give Illumina insight into how its customers are using Illumina products. (See PX7076 (Berry (Illumina) Dep. at 54-57); PX6056 (Illumina) at 051 [REDACTED]

2666. Ms. Berry testified that the volume of samples a customer requires and therefore the volume of reagents purchased could increase if the customer is pursuing a clinical trial or commercializing a product. (Berry (Illumina) Tr. 664-65; PX7076 (Berry (Illumina) Dep. at 24)).

2667. [REDACTED] } (See PX7076 (Berry (Illumina) Dep. at 24); PX7072 (deSouza (Illumina) IHT at 125-26) (*in camera*); PX2386 (Illumina) at 004 (Email from G. Shariat, Illumina, to N. Berry, Illumina, attaching Invitae 2020 NovaSeq Run Rate, Dec. 1, 2020) (*in camera*) ([REDACTED])).

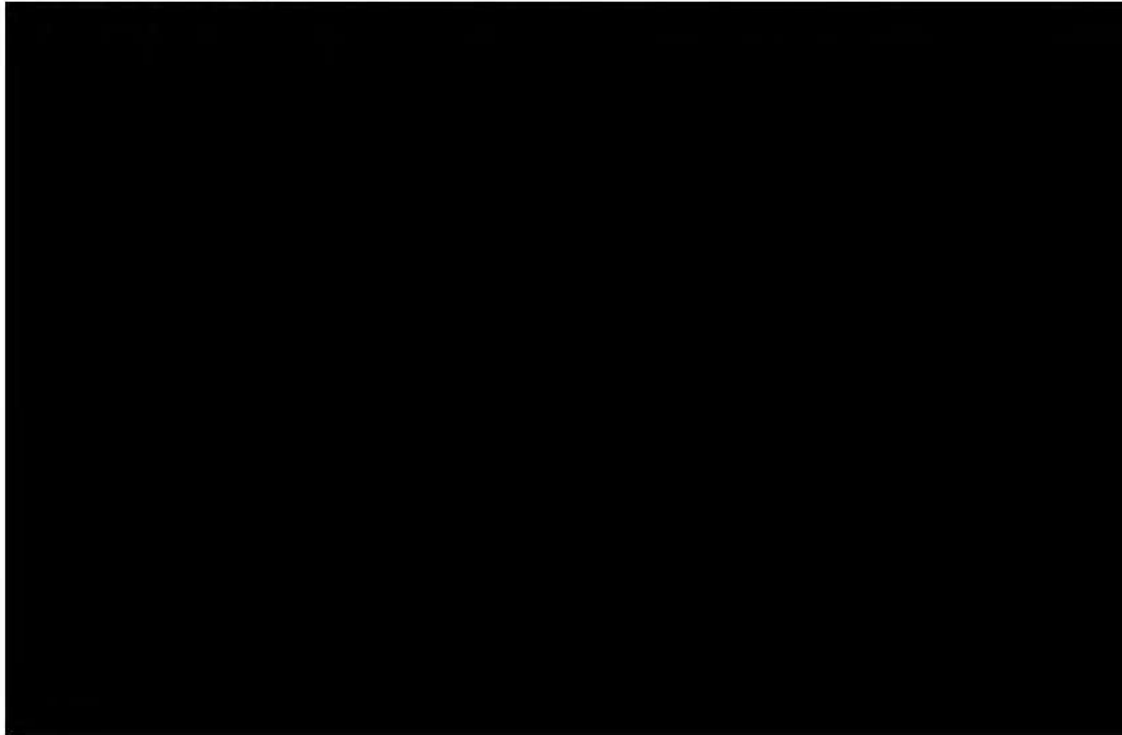
2668. [REDACTED] } (PX2314 (Illumina) at 002 (Email from C. Jennings, Illumina, to N. Berry, Illumina, Dec. 17, 2020 (*in camera*))).

2669. [REDACTED] (PX7063 (Berry (Illumina) IHT at 219) (*in camera*)).

2670. [REDACTED] } (PX2227 (Illumina) at 006 (Email from J. Flatley, Illumina, to A. Pierce, Illumina, attaching NIPT Update, Jan. 24, 2014) (*in camera*)).



(see inset); see also *infra* Section VII.D.3. (Illumina Identified and Used Similar Tools in the NIPT Market)).



{ }

2671. [REDACTED] (PX7109 (Daly (Singular Genomics) Dep. at 59) (*in camera*)).

2672. [REDACTED] (PX7109 (Daly (Singular Genomics) Dep. at 58) (*in camera*)). [REDACTED] (PX7109 (Daly (Singular Genomics) Dep. at 58-59) (*in camera*)).

(b) *Illumina Learns about Its Customers' Products through Embedded Software in Its NGS Platforms*

2673. Illumina CEO Mr. deSouza testified at trial that some Illumina customers' sequencers connect to Illumina via the internet to monitor the instrument or connect to Illumina's cloud-based data storage service. (deSouza (Illumina) Tr. 2383-85).

2674. Mr. deSouza testified that customers' Illumina sequencers can connect to Illumina remotely in two ways. The instrument can connect to Illumina to provide Illumina instrumentation metrics and for Illumina to "monitor the health of the instrument and proactively let [the customer] know if something is looking off." A customer also can connect its sequencers to Illumina's cloud-based data storage service. (deSouza (Illumina) Tr. 2383-85).
2675. Ms. Berry explained that Illumina's customers can choose to turn on "Proactive," a data sharing software embedded in Illumina's instruments. (PX7076 (Berry (Illumina) Dep. at 30)).
2676. By turning on Illumina's data-sharing Proactive software, a customer receives improved service from Illumina. (PX7076 (Berry (Illumina) Dep. at 36-37)).
2677. Ms. Berry testified that about 68 to 70 percent of Illumina instruments capable of connecting to Proactive are connected to the service. (Berry (Illumina) Tr. 853).
2678. [REDACTED] } (See PX7076 (Berry (Illumina) Dep. at 38-39); PX2386 (Illumina) at 004 (Email from G. Shariat, Illumina, to N. Berry, Illumina, attaching *Invitae 2020 NovaSeq Run Rate*, Dec. 1, 2020) (*in camera*) ([REDACTED])).
2679. [REDACTED] } (PX7055 (Otte (Freenome) IHT at 77) (*in camera*)).
2680. [REDACTED] } (PX7109 (Daly (Singular Genomics) Dep. at 59-60) (*in camera*)).
2681. [REDACTED] (PX7109 (Daly (Singular Genomics) Dep. at 59-60) (*in camera*)).
2682. [REDACTED] (PX7109 (Daly (Singular Genomics) Dep. at 60-61) (*in camera*)).

(c) *Illumina Learns about Its Customers' Products and Development Plans from Servicing Its Customers*

2683. [REDACTED] (PX7076 (Berry (Illumina) Dep. at 32-34) (*in camera*)).
2684. Ms. Berry testified that Illumina “may learn about . . . the market segment that the customer is wishing to use our products for, in a service and support interaction. It could be tech support . . . we may ask them some questions about, you know, what performance attributes are important to you, and you know, the customer may or may not disclose to us specifics about their intended use.” (PX7063 (Berry (Illumina) IHT at 35-36)).
2685. Ms. Berry testified at trial that Illumina also provides “troubleshooting” help to customers for issues with NGS instruments and “chemistry problem[s].” (Berry (Illumina) Tr. 846). Ms. Berry explained, “So, yeah, we -- we support the customer with respect to the pieces of the workflow whereby they’re using, you know -- that are absolutely dependent on the Illumina -- the parts of the workflow that we provide essentially, so the core sequencing piece primarily.” (Berry (Illumina) Tr. 846).
2686. Guardant relies on Illumina for service and support, as well as for “customization and optimization of our reagents.” (PX7105 (Getty (Guardant) Dep. at 60-62) (“Illumina provides support to us as a partner in sequencing” and “we rely on [Illumina] as we advance our technology. So more forward-looking technology aspects versus the day-to-day, you know, if we have, let’s say, reagent X and reagent X needs to be customized, maybe in the future state, you know, reagent Y could be created through a partnership with Illumina.”)).
2687. [REDACTED] (PX7105 (Getty (Guardant) Dep. at 61-62) (*in camera*)) ([REDACTED]); PX7094 (Nolan (Freenome) Dep. at 156-157) (*in camera*)) ([REDACTED])).
2688. [REDACTED] (PX7056 (Silvis (Tempus) IHT at 91-94) (*in camera*)).

(3) *Illumina Has Used Its Tools to Identify MCED Test Customers*

(a) *Illumina’s Customer Database and Supply Terms Classify Customers into Segments, Including Ones Related to MCED and Cancer Screening*

2689. Illumina tracks every product that its customers order using databases containing customer order and shipment history, and prices. (Berry (Illumina) Tr. 647). Illumina also tracks the services that it provides to customers. (Berry (Illumina) Tr. 647).

2690. Illumina utilizes Salesforce.com, a customer relationship management database, to store customer contact information, track sales opportunities, and generate price quotes. (Berry (Illumina) Tr. 659-660).
2691. Illumina’s customer database classifies customers based on the market segments in which they participate. (Berry (Illumina) Tr. 660-61; PX7076 (Berry (Illumina) Dep. at 54-57)). Illumina classifies customers in “approximately 10 or 12 segments,” including oncology testing. (Berry (Illumina) Tr. 660-61).
2692. Ms. Berry explained that Illumina classifies customers based on segments such as reproductive health, genetic disease testing, and oncology testing on the clinical side, and cell and molecular biology research, genetic disease research, cancer research, and microbiology on the research side. (PX7076 (Berry (Illumina) Dep. at 54-57)).
2693. Illumina’s Ms. Berry testified that, “I’m not familiar with all of the companies that offer oncology tests, but I’m, you know, familiar with the companies that purchase products from Illumina for the purposes of offering oncology tests.” (PX7063 (Berry (Illumina) IHT at 30-31)).

(b) *Revealing Its Knowledge of Its MCED Customers*

[REDACTED]

2694. After the announcement of the Acquisition, Illumina decided to contact its “largest onc[ology] testing customers or those specifically participating in the early detection space” to inform them of the Acquisition and offer them long-term supply agreements, in an attempt to alleviate their concerns about the transaction. (PX2302 (Illumina) at 001 (Email from N. Berry, Illumina, to C. Fideler, M. Gallad, et al., Illumina, Sept. 21, 2020)).

2695. [REDACTED] (Berry (Illumina) Tr. 752-53 (*in camera*)).

2696. [REDACTED] } (Berry (Illumina) Tr. 753 (*in camera*)).

2697. [REDACTED] } (Berry (Illumina) Tr. 937-38 (*in camera*)).  
[REDACTED] } (Berry (Illumina) Tr. 938 (*in camera*)).

2698. [REDACTED] (Berry (Illumina) Tr. 750-51 (*in camera*)).

2699. [REDACTED] } (Berry (Illumina) Tr. 753-55 (*in camera*)).

2700. Mr. deSouza’s comments at the Cowen Liquid Biopsy Summit on September 24, 2020 revealed that Illumina analyzed which of its customers a combined Illumina/Grail would compete with: “[A]bout 20 [Illumina] customers out of about 6,600 have said that they have an interest in exploring [the early detection of cancer] space. Those 20 customers represent roughly about 2% of our revenue.” (PX2575 (Illumina) at 065 (Email from T. Friedman, Illumina, to J. Cunningham, Illumina, attaching Edited Transcript, ILMN.OQ – Illumina Inc at Cowen Liquid Biopsy Summit (Virtual), Sept. 29, 2020); *see also* deSouza (Illumina) Tr. 2220-22). Mr. deSouza confirmed that those 20 customers include Guardant, Roche, Freenome, Singlera, Exact/Thrive, and Grail. (deSouza (Illumina) Tr. 2220-23; PX2575 (Illumina) at 065 (Email from T. Friedman, Illumina, to J. Cunningham, Illumina, attaching Edited Transcript, ILMN.OQ – Illumina Inc at Cowen Liquid Biopsy Summit (Virtual), Sept. 29, 2020); PX2031 (Illumina) at 005 n.2 (Illumina, Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 24, 2020) (listing Guardant, Thrive, Freenome, Singlera, Exact, and Grail)).

2701. In a text message dated September 16, 2020, four days prior to the announcement of Illumina’s proposed acquisition of Grail, Ms. Berry stated in an exchange with Jeremy Preston, Illumina’s Vice President of Global Regional Marketing, that she thought that Illumina’s acquisition of Grail would result in Illumina being perceived as competing with their customers in the same segment, including Guardant, Thrive, Freenome, Natera, Tempus, and FMI. (PX2158 (Illumina) at 001 (Mobile text chain between N. Berry, Illumina, and J. Preston, Illumina, Sept. 16, 2020) (“[Preston:] “Do you think grail will be perceived as competing with our customers? [Berry:] Yes for those that are in the same segment [Preston:] Guardant, Thrive, Freenome, Natera, Tempus, FMI. . . [Berry:] Yes exactly”); *see also* (Berry (Illumina) Tr. 743-44 (*in camera*))). Ms. Berry texted that “[w]e’ve already gotten some WTF emails from customers.” (PX2158 (Illumina) at 001 (Text message between N. Berry, Illumina, and J. Preston, Illumina, Sept. 16, 2020)).

## 2. Illumina Has a Multitude of Tools to Foreclose or Reduce the Competitiveness of Grail’s MCD Test Rivals

2702. Illumina knows that “[s]creening represents the largest market opportunity within the broader ctDNA market, but the key bottleneck to market development is the cost of sequencing.” (PX2712 (Illumina) at 029 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, attaching Python: A Revolution in Early Cancer Detection Presentation, Dec. 3, 2019)).

2703. As documented in Section V. above, each MCED witness testified that they only have one option for NGS supplier—Illumina.

a) Illumina Can Increase Prices of Its Instruments and Reagents

2704. [REDACTED] } (See PX7051 (Lengauer (Third Rock Ventures) IHT at 127-28) (*in camera*); PX7047 (Cooper (Progenity) IHT at 54)).

2705. [REDACTED] } (PX6090 (Scott Morton Report) ¶ 178 (*in camera*)).

2706. All pricing programs must be approved by Illumina’s Pricing Committee. (PX6056 (Illumina) at 038 (Illumina, Narrative Response to Second Request, Mar. 1, 2021); PX7072 (deSouza (Illumina) IHT at 13-14 (*in camera*)).

2707. [REDACTED] } (PX7123 (Fellis (Illumina) Dep. at 18) (*in camera*)).

2708. The pricing committee approves Illumina’s pricing strategy. “As product managers in the product management function develop[] a pricing strategy around a given set of products, that would go to the pricing committee for review and approval.” (PX7123 (Fellis (Illumina) Dep. at 20)). With very few exceptions, the pricing committee approves all pricing strategies provided by product managers. (PX7123 (Fellis (Illumina) Dep. at 20)).

2709. [REDACTED] (PX6056 (Illumina) at 038 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)) ( [REDACTED] })). [REDACTED] } (PX7072 (deSouza (Illumina) IHT at 15) (*in camera*)).

2710. [REDACTED] } PX6056 (Illumina) at 038 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

2711. [REDACTED] (PX7072 (deSouza (Illumina) IHT at 14) (*in camera*)). [REDACTED]

[REDACTED] } (PX7072 (deSouza (Illumina) IHT at 15) (*in camera*)).

2712. [REDACTED] (PX7072 (deSouza (Illumina) IHT at 17) (*in camera*)); PX7123 (Fellis (Illumina) Dep. at 24-25) (*in camera*)).

2713. [REDACTED] } (PX7123 (Fellis (Illumina), Dep. at 21, 30 (*in camera*)) ( [REDACTED] })).

2714. [REDACTED] } (PX7123 (Fellis (Illumina), Dep. at 22) (*in camera*)) ( [REDACTED] )).

2715. Guardant’s Mr. Getty testified that “whatever terms, conditions, and pricing they [Illumina] want to put forward, they can do so. And they can use their monopoly power in order to . . . drive to whatever conclusion they’d like.” (PX7105 (Getty (Guardant) Dep. at 67-68)).

2716. [REDACTED] } (Getty (Guardant) Tr. 2524, 2629-30 (*in camera*)).

2717. Guardant’s CEO testified that, “as customer for Illumina, we are an important customer, but we do not drive, you know, a significant portion of their revenue such that, you know, they would be dependent on Guardant.” (Getty (Guardant) Tr. 2524).

2718. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 182-83) (*in camera*)).

2719. Dr. Gao testified that in negotiations with Illumina, “their [Illumina’s] way is my way or the highway. If you gave [Illumina] that profit margin, well, [Illumina] -- you know, [Illumina] can allow you to survive. If not, you just die.” (PX7042 (Gao (Singlera) IHT at 87-88)).

2720. [REDACTED]

[REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 180-81) (*in camera*)).

2721. In an internal Grail e-mail, Grail’s Research Operations Manager Minyong Chung wrote with regard to price negotiations with Illumina that “[n]egotiating with ILMN alone is very tricky because of their unique market position (basically a monopoly) . . . .” (PX4019 (Grail) (Email from M. Chung, Grail, to J. Wong, Grail, Sept. 29, 2018)).

(1) [REDACTED]

2722. [REDACTED] } (PX2608 (Illumina) at 001, 003 [REDACTED] *in camera*); see PX7123 (Fellis (Illumina) Dep. at 72-73) (*in camera*)).

2723. [REDACTED] (PX2608 (Illumina) at 003 [REDACTED] (*in camera*)).

2724. [REDACTED] (PX2608 (Illumina) at 001, 004 [REDACTED] (*in camera*)).

(a) [REDACTED]

2725. [REDACTED] (See e.g., PX2306 (Illumina) at 011 [REDACTED] (*in camera*); see PX2387 (Illumina) at 002 (Email from WF-BATCH, Illumina, to N. Berry, Illumina, Apr. 19, 2018) (*in camera*) ([REDACTED] })).

2726. [REDACTED] } (PX7076 (Berry (Illumina) Dep. at 115-116, 169-170) (*in camera*); see PX7123 (Fellis (Illumina) Dep. at 53-54) (*in camera*)).

2727. [REDACTED] } (PX7076 (Berry (Illumina) Dep. at 172-173, 177) (*in camera*)).



2728. [REDACTED]

2729. [REDACTED]

2730. [REDACTED]  
(*in camera*)).

2731. [REDACTED] } (Berry (Illumina) Tr. 774)  
(*in camera*).

2732. [REDACTED] (Berry (Illumina) Tr. 775-76) (*in camera*).

2733. [REDACTED] } (Berry (Illumina) Tr. 776) (*in camera*).

2734. [REDACTED] (PX2688 (Illumina) at 001 (Email from WF-BATCH, Illumina, to R. Graff, Illumina, attaching Quote Approval Request, Feb. 1, 2018) (*in camera*)).

2735. [REDACTED] (Berry (Illumina) Tr. 780) (*in camera*). }  
[REDACTED] (PX7076 (Berry (Illumina) Dep. at 115-119); *see also* PX7123 (Fellis (Illumina) Dep. at 58-59) (*in camera*)).

2736. Illumina often provides the customer with [REDACTED] } (PX7076 (Berry (Illumina) Dep. at 155-156) (*in camera*)). }  
[REDACTED] (PX2631 (Illumina) at 001 (Quote Approval Request, Feb. 26, 2018) (*in camera*)).

2737. [REDACTED] PX2379 (Illumina) at 001 (Email from N. Berry, Illumina, to D. Blevins et al., Illumina, attaching Quote Approval Request, Feb. 14, 2019) (in camera) ([REDACTED]); PX2631 (Illumina) at 001 (Email from WF-BATCH, Illumina, to N. Berry, Illumina, attaching Quote Approval Request, Feb. 26, 2018) (in camera) ([REDACTED])).

2738. [REDACTED] (PX2377 (Illumina) at 001 (Email from WF-BATCH, Illumina, to N. Berry, Illumina, attaching Quote Approval Request, Oct. 17, 2018) (in camera)).

2739. [REDACTED] (PX2378 (Illumina) at 001-02 (Email from WF-BATCH, Illumina, to N. Berry, Illumina, attaching Quote Approval Request, Dec. 27, 2018) (in camera)).

2740. [REDACTED] } (Berry (Illumina) Tr. 779) (in camera)). [REDACTED] } (Berry (Illumina) Tr. 779) (in camera)).

2741. [REDACTED] } (Berry (Illumina) Tr. 779) (in camera)).

2742. [REDACTED] (PX7076 (Berry (Illumina) Dep. at 174) (in camera)).

2743. As detailed below in Section VII.D.2.c.4.a.iii., [REDACTED] }

(b) [REDACTED]

2744. [REDACTED] } (Berry (Illumina) Tr. 789-790) (in camera); PX7076 (Berry (Illumina) Dep. at 177) (in camera)).

2745. [REDACTED] } (PX7076 (Berry (Illumina) Dep. at 177) (in camera) [REDACTED] }; PX7076 (Berry (Illumina) Dep. at 174) (in camera) [REDACTED] .

2746. [REDACTED] } (PX7076 (Berry (Illumina) Dep. at 177) (*in camera*)).

2747. Illumina uses the different price sensitivities of different segments in determining how to price its products. (PX7076 (Berry (Illumina) Dep. at 174).

2748. [REDACTED] } (PX7076 (Berry (Illumina) Dep. at 173-74)); (Berry (Illumina) Tr. 784-85) (*in camera*)).

2749. [REDACTED] } (PX2391 (Illumina) at 001 (Email from N. Berry, Illumina, to P. Dueppen, Illumina, Jan. 29, 2021) (*in camera*)).

(c) *Illumina and Illumina’s Oncology Customers Confirm Illumina Uses Different Pricing and Discounting Based on Its Customers’ Product Lines, Including Pricing MCED Tests Differently from Single-cancer Tests*

2750. Sean George, CEO of Invitae, a customer of Illumina, testified that Illumina charges “different pricing or price tiers or price volume tiers, depending on what we’re doing.” (PX7081 (George (Invitae) Dep. at 82-85)). Mr. George testified that “there’s always been a kind of differential pricing for that – the core components of the Illumina sequencing based on what the application was, based on what you were using the sequencing for.” (PX7081 (George (Invitae) Dep. at 82-85)).

2751. Matthew Cooper, Chief Scientific Officer at Progenity, a customer of Illumina, testified that “we have to buy the fancy reagents in a different-colored box to run an NIPT versus cheap reagents for research use in doing [product] discovery purposes.” (PX7082 (Cooper (Progenity) Dep. at 124-25)).

2752. [REDACTED] } (PX7076 (Berry (Illumina) Dep. at 260-61) (*in camera*)).

2753. [REDACTED] } (See PX7076 (Berry (Illumina) Dep. at 260-61) (*in camera*)).

2754. [REDACTED] } (PX7076 (Berry (Illumina) Dep. at 260-61) (*in camera*)).

2755. Illumina sent Singlera a draft IVD rights term sheet, which included a \$40 per sample “Market Access Fee” (in addition to other fees and a 10 percent revenue share). (PX7042 (Gao (Singlera) IHT at 78-80); see PX8516 (Singlera) at 006 (Singlera, Email attaching Singlera-Illumina Draft IVD NextSeqDX Term Sheet, June 20, 2020)).

2756. Illumina’s “Market Access Fee” distinguished between a single-cancer test like Singlera’s ColonES and a pan-cancer test like Singlera’s PanSeer. (PX7042 (Gao (Singlera) IHT at 78-80); see PX8516 (Singlera) at 006 (Email from J. Leite, Illumina, to G. Gao, Singlera, attaching Singlera-Illumina Draft IVD NextSeqDX Term Sheet, June 20, 2020) (assigning a payment structure for each cancer indication, capping “pan-cancer Class III claims” at \$10 million)).

2757. Under Illumina’s proposed terms to Singlera, a “pan-cancer” test would cost 2.5 times more than a single-cancer test. (PX7042 (Gao (Singlera) IHT at 78-81); see PX8516 (Singlera) at 006 (Email from J. Leite, Illumina, to G. Gao, Singlera, attaching Singlera-Illumina Draft IVD NextSeqDX Term Sheet, June 20, 2020) (assigning a payment structure for each indication, capping “pan-cancer Class III claims” at \$10 million)).

(d) *Illumina Can Target MCED Customers Via Field-of-use Restrictions that Illumina Includes in Its Agreements with Customers.*

2758. [REDACTED] } (Felton Tr. 2062 (*in camera*)).

2759. [REDACTED] (PX7079 (Flatley (Illumina) Dep. at 127) (*in camera*)).

2760. [REDACTED] } (PX7053 (Fesko (Natera) IHT at 57-58) (*in camera*)).

2761. Mr. Flatley explained that Illumina has invoked the field of use clause when Illumina was [REDACTED] } (PX7079 (Flatley (Illumina) Dep. at 127) (*in camera*)).

(i) *Illumina Has Previously Used Field-of-Use Restrictions to Limit Discounts to Product Lines that Did Not Compete with an Illumina Business Line*

2762. [REDACTED] (PX7060 (Naclerio (Illumina) IHT at 126-28) (*in camera*)).

2763. [REDACTED] } (PX7076 (Berry (Illumina) Dep. at 216-17) (*in camera*)).

2764. [REDACTED] (PX2441 (Illumina) at 003 (Email from N. Naclerio, Illumina, to M. Rabinowitz, Natera, et al. attaching Natera NIPT Supply Agreement Terms, May 4, 2013)) (*in camera*)).

2765. [REDACTED] } (PX7113 (Rabinowitz (Natera) Dep. at 114) (*in camera*)).

2766. [REDACTED] } (PX8379 (Natera) at 003 Aug. 16, 2013) (*in camera*)).  
[REDACTED] (PX8379 (Natera) at 020 (*in camera*)).  
[REDACTED] (PX8379 (Natera) at 023

2767. [REDACTED] (RX1899 (Illumina) at 003 [REDACTED] PX2241 (Illumina) at 001 (Letter from C. Moehle, Illumina, to K. Song, Ariosa, Jan. 10, 2014)).

2768. According to Illumina, the Customer Field of Use provisions in Ariosa's supply agreement prohibited Ariosa from performing fetal gender determination using Illumina products. (PX2241 (Illumina) at 001 (Letter from C. Moehle, Illumina, to K. Song, Ariosa, Jan. 10,

2014)). On January 10, 2014, Illumina sent a breach letter to Ariosa alleging, among other things, that Ariosa's sale of a sequencing-based prenatal test that reported fetal gender represented a breach of its Sale and Supply Agreement with Illumina. (PX2241 (Illumina) at 001 (Letter from C. Moehle, Illumina, to K. Song, Ariosa, Jan. 10, 2014)).

2769. [REDACTED] (See, e.g., PX2134 (Illumina) at 001 [REDACTED])

2770. [REDACTED] (See PX2134 (Illumina) at 001 [REDACTED]) PX2095 (Illumina) at 003, 008 [REDACTED]; PX2200 (Illumina) at 002 (Email from J. Leite, Illumina, to M. Van Oene et al., Illumina, Nov. 3, 2020 [REDACTED])

2771. [REDACTED] (See PX2095 (Illumina) at 003, 008 [REDACTED]) ; PX2200 (Illumina) at 002 (Email from J. Leite, Illumina, to M. Van Oene, Illumina, Nov. 3, 2020) [REDACTED]

2772. As explained in detail below in Sections VII.D.2. (Illumina Identified and Used Similar Tools in the Oncology Therapy Selection Market) and VII.D.3. (Illumina Identified and Used Similar Tools in the NIPT Market), when vertically integrated, Illumina has used many tools to inhibit its NGS customers that also compete with Illumina's clinical product portfolio.

(2) Illumina’s Pricing Strategy Gives It the Ability to Increase Prices Anywhere along the Value Chain—from the Sale of Instruments and Consumables to the Provision of Services—and Target Specific Applications or Customers by Altering the Discounts it Offers

2773. [REDACTED]  
(PX7123 (Fellis (Illumina) Dep. at 27-28, 29, 30, 35) (*in camera*)).

2774. [REDACTED] (See e.g., PX2306 (Illumina) at 011-12 [REDACTED] (*in camera*)).

2775. [REDACTED] } (PX7089 (Naclerio (Illumina) Dep. at 196-197) (*in camera*)).

2776. [REDACTED] (PX7089 (Naclerio (Illumina) Dep. at 199-200) (*in camera*)).

2777. [REDACTED]  
(See, e.g., PX7042 (Gao (Singlera) IHT at 76-77) (noting Illumina’s “technology access fee of \$3 million”); PX7049 (Bailey (PGDx) IHT at 121-125) (*in camera*) ([REDACTED] })).

2778. As described in Sections VII.D.2. (Illumina Identified and Used Similar Tools in the Oncology Therapy Selection Market) and VII.D.3. (Illumina Identified and Used Similar Tools in the NIPT Market), Illumina has previously used fees—in various forms—when vertically integrated in the therapy selection and NIPT markets to control and customize the price of its instruments, consumables, and services.

2779. [REDACTED]  
[REDACTED] (PX6090 (Scott Morton Report) ¶ 182 (*in camera*)). [REDACTED]

[REDACTED]

[REDACTED]

(PX6090 (Scott Morton Report) ¶ 182 (*in camera*)).

(3) With Its Price Control, Illumina Could Offer Less Favorable Terms to MCED Test Developers, Affecting Their Profitability and Competitiveness, and Harming Innovation

2780. Dr. William Cance, Chief Medical and Scientific Officer at American Cancer Society, stated in a Declaration, “If development costs increase, companies that would otherwise have worked towards developing these tests may struggle to carry their ideas forward to where they can become a reality for doctors and patients.” (PX8398 (Cance (American Cancer Society) Decl. at ¶ 12)).

2781. William Getty, Senior Vice President of the Commercial Screening Division at Guardant, testified that Illumina has the ability to act so that “profitability is squeezed for other manufacturers such that over time, those manufacturers are rendered nonexistent. And ultimately then innovation slows down because there’s no advantage for Illumina to advance their technology” and “patients will be negatively impacted.” (PX7105 (Getty (Guardant) Dep. at 74-76)).

2782. [REDACTED] (PX7105 (Getty (Guardant) Dep. at 72-73) (*in camera*)).

2783. Mr. Getty explained that “as a public company . . . profitability is critical to our shareholders. And very quickly we would find it very difficult to invest in the R&D necessary or the commercialization necessary to make, you know, improvements and impact patients’ lives.” (PX7105 (Getty (Guardant) Dep. at 32-33)).

2784. [REDACTED] (PX7055 (Otte (Freenome) IHT at 110) (*in camera*)).

2785. Dr. Gary Gao, Co-Founder and Scientific Advisor for Singlera, expressed that “Illumina can jack up the price of [its] reagent or machine . . . and then we will not be able to compete.” (PX7042 (Gao (Singlera) IHT at 130)).

2786. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 194) (*in camera*)).

2787. [REDACTED]



[REDACTED] } (PX8324 (Roche) at 003 [REDACTED]  
(in camera)).

2788. [REDACTED]  
[REDACTED] } (PX8324 (Roche) at 005 [REDACTED]  
(in camera)).

2789. [REDACTED]  
[REDACTED] (PX8324 (Roche) at 005 [REDACTED]  
(in camera)).

b) ILLUMINA Can Delay or Foreclose MCEd Rivals' Access to New NGS Technology and Favor and Advantage Grail to the Exclusion and Disadvantage of Grail's MCEd Rivals

- (1) ILLUMINA Regularly Releases New Sequencers, Reagents, and Upgrades to its NGS Technology

2790. ILLUMINA continuously makes improvements and updates to the performance and feature set of its existing platforms:

JUDGE CHAPPELL: Do you know if there are frequent – I'm not sure of the terminology – but software updates or something that would need to be added to make the machine perform properly?

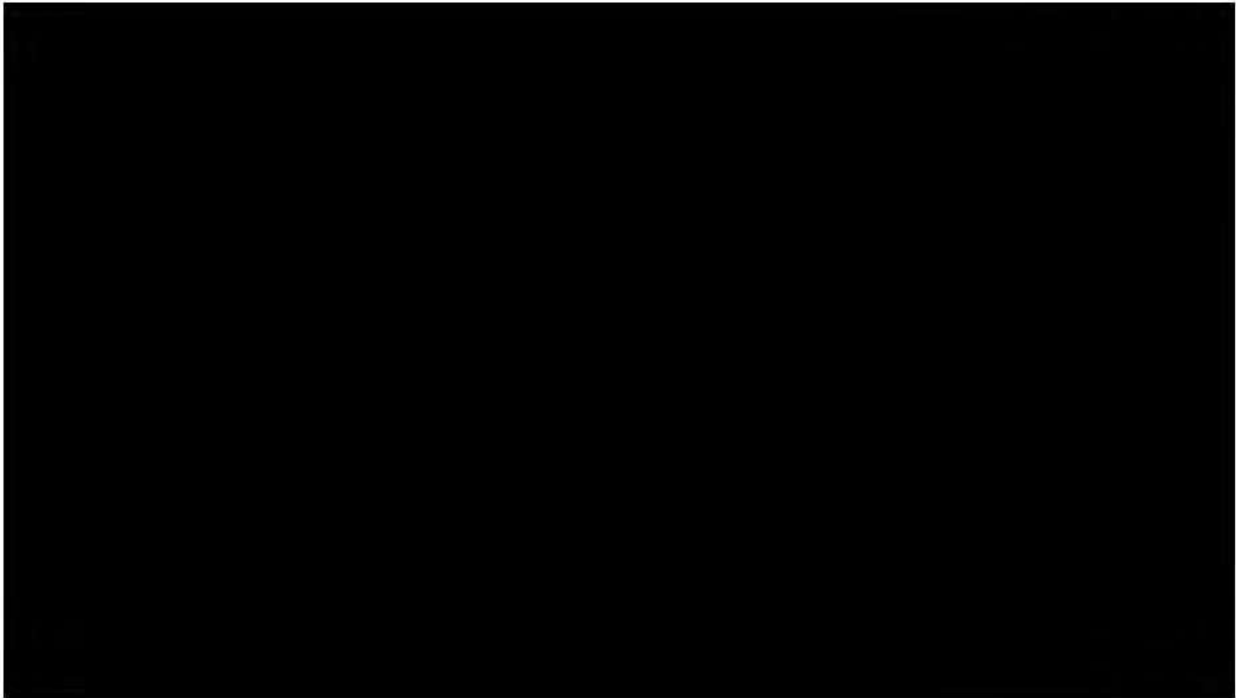
THE WITNESS [Nicole Berry, ILLUMINA Senior Vice President and General Manager of the Americas Commercial Region]: Sure. So we are continuously seeking to improve performance and, you know, the feature set of our instruments and user friendliness as it relates to things like software. So, yes, software updates are something that we would typically provide and make part of our continuous sort of update and improvement process.

Those oftentimes could be actually administered remotely. If the customer opted into sort of, you know, a remote connectivity, we could potentially just push an update to the customer's instrument without having to actually go into the lab and, you know, sit at it and put disks in a hard drive, you know, the old-fashioned way.

(Berry (ILLUMINA) Tr. 675-76).

2791. ILLUMINA's Ms. Berry testified about ILLUMINA's "track record in terms of our technology innovation and new product introduction process," stating that ILLUMINA has introduced new instrument platforms and new chemistries within instrument platforms "on a very regular basis." (Berry (ILLUMINA) Tr. 714).

2792. [REDACTED] (PX7072 (deSouza (Illumina) IHT at 247) (*in camera*)).
2793. Illumina updates its sequencers' software from time to time. (deSouza (Illumina) Tr. 2383).
2794. [REDACTED] (See PX2169 (Illumina) at 024 (Illumina Strategic Plan 2021-2025: Board Discussion Document, Oct. 23, 2020) (*in camera*)).
2795. [REDACTED] } (See PX7107 (deSouza (Illumina) Dep. at 271) (*in camera*)).  
[REDACTED] } (PX2558 (Illumina) at 005-06 (Email from E. Milovic, Illumina, to F. deSouza, Illumina, attaching Board of Directors Executive Session, Feb. 9, 2021) (*in camera*); see also PX2560 (Illumina) at 007 [REDACTED] (*in camera*); PX7067 (Blanchett (Illumina) IHT at 194-95) (*in camera*)).
2796. [REDACTED] } (RX1994 (Illumina) at 023 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)).
2797. [REDACTED] (deSouza (Illumina) Tr. 2277 (*in camera*)).
2798. [REDACTED] } (deSouza (Illumina) Tr. 2269 (*in camera*)).
2799. As detailed above in Section V.G.4. (Even if Another NGS Platform Entered the U.S. Market Comparable to Illumina's Current Platform, Illumina Plans to Continue to Improve its Existing Platform), [REDACTED] }
2800. [REDACTED] } (RX1994 (Illumina) at 025 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)).



{ }

- 2801. [REDACTED] (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)). [REDACTED] (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)).
- 2802. [REDACTED] (RX1994 (Illumina) at 029 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)).
- 2803. [REDACTED] (RX1994 (Illumina) at 037 (Email from S. Muppaneni, Illumina, to P. Febbo, Illumina, attaching Illumina 2021-2025 Strategic Plan Presentation, Nov. 5, 2020) (*in camera*)).
- 2804. [REDACTED] (See PX7076 (Berry (Illumina) Dep. at 211-212) (*in camera*)).

(2) When Illumina Releases New NGS Equipment, MCED Customers Rely on Illumina for Installation, Technical Support, and Product Development

2805. When customers seek to upgrade their NGS instruments, Illumina will send a technician to get the new instruments “up and running and to assist in troubleshooting matters.” (PX7082 (Cooper (Progenity) Dep. at 87)).
2806. Illumina’s Nicole Berry testified that Illumina “work[s] with a customer to confirm that the instrument is performing to spec and the general purpose reagents, the sequencing kits that they buy from us to sequence samples using their assay, are performing to our specifications.” (PX7076 (Berry (Illumina) Dep. at 151-152)).
2807. When Illumina releases a new product, Illumina provides customers with support for “how to validate” the new product’s functionality. (PX7080 (Silvis (Tempus) Dep. at 131)). Tempus’s Lauren Silvis testified, “it could be very difficult to run a successful validation if there were questions we couldn’t figure out or troubleshoot on our own and . . . [Illumina] wouldn’t answer questions about what the issues might be or how to solve them.” (PX7080 (Silvis (Tempus) Dep. at 131)).
2808. [REDACTED] } (PX7076 (Berry (Illumina) Dep. 154) (*in camera*)).
2809. At trial, Illumina CEO Mr. deSouza referred to helping customers with installing machines as a frequent issue. (deSouza (Illumina) Tr. 2442).

(3) Illumina Can Delay or Foreclose MCED Rivals’ Access to New Technology to Advantage Grail and Disadvantage Grail’s Rivals

2810. Illumina’s Nicole Berry testified that Section 4(c) of the Open Offer does not prevent Grail from having knowledge of Illumina’s new technology before other companies developing oncology tests. (Berry (Illumina) Tr. 708).
2811. Under the Open Offer, Grail can learn the specifications of new Illumina sequencers before its rival MCED test developers. (Berry (Illumina) Tr. 708).
2812. As discussed below in Section VIII.A.3. (Illumina’s Open Offer Fails to Remedy Anticompetitive Harm from the Merger), [REDACTED] } (Getty (Guardant) Tr. 2552-53 (*in camera*)).
2813. Dr. Bert Vogelstein testified that advanced knowledge of “future product developments and refinements” from Illumina “could substantially alter research and development in the field and the nature of the test products that are eventually produced.” (PX8400 (Vogelstein (John Hopkins University) Decl. ¶ 9)).

2814. Guardant’s Bill Getty testified that “it is not any bit speculative” that Illumina could provide new technology to Grail to aid Grail’s test over its rivals:

[S]o it is not any bit speculative to believe to that as Illumina continues to advance their technology, that they would advance that technology and allow for a subsidiary or partner, however it’s structured, in GRAIL access to that technology, which may convey a benefit to them around their testing in terms of sensitivity and specificity, which their advancements in sequencing have done over time.

So there is largely a precedent there for their advancement. And so giving early access to an organization that you are tied up with translates into a highly-advantaged test in the marketplace, thus, you know, patient and potentially -- not potentially -- but physician preference -- potentially patient preference, I should say, and therefore you maintain further your competitive advantage as Illumina.

(PX7105 (Getty (Guardant) Dep. at 73-74)).

2815. Bill Getty of Guardant testified that Illumina could “provide favored status or development opportunities to their internal partners in Grail, which would convey potentially a lack of opportunity for us to advance our technology at a faster rate, and . . . thus hurt us competitively.” (PX7105 (Getty (Guardant) Dep. at 69-71)).

2816. Guardant’s Bill Getty testified that without access to Illumina’s latest technology, Guardant will not be able to offer patients the best performing or the lowest cost test. (PX7105 (Getty (Guardant) Dep. at 74-75)).

2817. Mr. Getty described the scenario where “the profitability is squeezed for other manufacturers such that over time, those manufacturers are rendered nonexistent. And ultimately then innovation slows down because there’s no advantage for Illumina to advance their technology such that patients will be negatively impacted.” (PX7105 (Getty (Guardant) Dep. at 74-76)).

2818. [REDACTED] } (Getty (Guardant) Tr. 2543  
(*in camera*)).

2819. One of Mr. Getty’s concerns about the Proposed Acquisition is that advanced notice of information about a new sequencer in development from Illumina could give Grail a “significant head start” on developing the next version of its MGED assay. (Getty (Guardant) Tr. 2518-19).

2820. [REDACTED] (PX7058 (Conroy (Exact) IHT at 241-242) (*in camera*)).

2821. [REDACTED]

(PX7051 (Lengauer (Third Rock Ventures) IHT at 88-89) (*in camera*)).

2822. [REDACTED]

[REDACTED]

(Lengauer (Third Rock Ventures) Tr. 197-98 (*in camera*)).

2823. [REDACTED]

} (PX7085 (Harada (Exact) Dep. at 204-205) (*in camera*)).

2824. [REDACTED]

(PX2598 (Illumina) at 002 (Email from D. Daly, Illumina, to L. Leigh, Illumina, et al., Apr. 11, 2018) (*in camera*)).

2825. [REDACTED]

} (PX2152 (Illumina) at 001 (Text message from S. Tousi, Illumina, Apr. 23, 2020) (*in camera*)).

2826. Illumina’s CEO told the Court at trial that Illumina cannot, and will not, make improvements to technology specifically geared toward Grail. (deSouza (Illumina) Tr. 2443-44; 2446-47).

2827. [REDACTED]

(PX2541 (Illumina) at 008 (Illumina, Interim Review K2-Grail (aka Grail “Pendragon”), Feb. 2, 2017) (*in camera*)).

2828. As discussed below in Sections VII.A.2.e. (Illumina Can Alter its NGS Products to Disadvantage Grail’s MCED Rivals), VIII.A.3.c.1. (Illumina Can Customize Its Consumables to Favor Grail), and VII.A.3.n.1. (Rather Than Refusing to Sell MCED Test



2832. [REDACTED]

[REDACTED]

(Conroy (Exact) Tr. 1588-89 (*in camera*)).

2833. [REDACTED]

(Conroy (Exact) Tr. 1596 (*in camera*)).

2834. [REDACTED]

} (Conroy (Exact) Tr. 1596-97 (*in camera*)).

2835. [REDACTED] (PX7051)

(Lengauer (Third Rock Ventures) IHT at 201) (*in camera*)).

2836. Helio’s former CEO, Dr. Chahine, testified that he envisioned “a million different ways” that Illumina and Helio could have strategically collaborated “to work as a partner to try to solve the consumer’s products and not have to be guarded about your plans and your strategy and your consumer data and your physician data and things like that.” He also testified that if the Illumina-Grail transaction closed, “this is obvious – I’d just have to be more guarded.” (PX7077 (Chahine (Helio) Dep. at 65-67)).

(2) MCED Test Developers Testified that Illumina Controls the NGS Supply Chain, and Developers’ Reliance on Illumina Creates Continuing Business Risk

2837. [REDACTED]

(PX7109 (Daly (Singular Genomics) Dep. at 56) (*in camera*)).

2838. [REDACTED]



- [REDACTED] } (PX7090 (Sood (Guardant) Dep. at 119-21) (*in camera*)).
2839. William Getty, Guardant’s Senior Vice President of Commercial, Cancer Screening Core, expressed that if Illumina stopped supplying Guardant, or failed to supply products in a timely manner, then Guardant’s business “would be nonexistent.” (PX7105 (Getty (Guardant) Dep. at 58)).
2840. Mr. Getty testified that any disruption in Guardant’s relationship with Illumina could adversely affect Guardant’s ability to conduct its business and generate revenue. (Getty (Guardant) Tr. 2684).
2841. [REDACTED] } (PX7045 (Chudova (Guardant) IHT at 105-109) (*in camera*)).
2842. [REDACTED] } (PX7100 (Chudova (Guardant) Dep. at 85) (*in camera*)).
- [REDACTED] } (PX7100 (Chudova (Guardant) Dep. at 85-87) (*in camera*)).
- [REDACTED] } (PX7100 (Chudova (Guardant) Dep. at 86-87) (*in camera*)).
- [REDACTED] (PX7100 (Chudova (Guardant) Dep. at 87) (*in camera*)).
2843. Mr. Getty explained that Guardant’s dependence on Illumina creates business risk “[b]ecause Illumina is a sole supplier for us and our business rests on our ability to sequence and leverage [Illumina’s] services in order to maintain those sequencers.” (Getty (Guardant) Tr. 2684-85).
2844. Mr. Getty expressed that Illumina is “in a position where they could take significant advantage by kneecapping our ability to run our lab, which would of course flow through to our inability to compete.” (PX7105 (Getty (Guardant) Dep. at 68-69)).
2845. [REDACTED] (PX7040 (Getty (Guardant) IHT 88 (*in camera*))).
2846. In its annual report, Guardant identified Illumina as its “sole supplier of sequencers and as the sole provider of maintenance and repair services for these sequencers,” and indicated that “[a]ny disruption in operations of Illumina . . . could materially and adversely impact

our supply chain and laboratory operations of our precision oncology platform and thus our ability to conduct our business and generate revenue.” (PX0153 at 47 (Guardant 2020 Form 10-K, Feb. 25, 2021)).

2847. [REDACTED] } (Conroy (Exact) Tr. 1585 (*in camera*)).

2848. [REDACTED] } (Conroy (Exact) Tr. 1585 (*in camera*)).

2849. Dr. Gao testified that Illumina is “obviously the 800-pound gorilla in the room.” (Gao (Singlera) Tr. 2947-48). Dr. Gao explained, “Illumina control[s] the supply chain for all the NGS-based early cancer detection technology, not only for Singlera, but for other companies, too. So I don’t think I’m alone in this -- seeing this 800-pound gorilla.” (Gao (Singlera) Tr. 2947-48, 2951).

2850. Dr. Gao explained his concerns related to Illumina’s “control” of the supply chain:

[T]he problem is . . . cost is very essential for any -- basically marketing any product or any investor. Illumina can choose the price, set the price of the sequencer, and also the reagent, but Grail is a -- if it’s part of the Illumina public company, they can lose on the reagent and Grail can still charge whatever -- Illumina can charge them a high price. They don’t care. They are one company. But for us, we cannot have another cost center to transfer the cost, so we have to eat the high reagent and equipment cost. We -- you know, we cannot decrease our price or we will lose.

(Gao (Singlera) Tr. 2951).

2851. Dr. Gao testified that “Grail [is] doing something similar in direct competition with [Singlera and] Illumina is supplying . . . all essential equipment and reagents. [Illumina] could potentially . . . prevent us from develop[ing the PanSeer test] and delivering a cost-effective product.” (Gao (Singlera) Tr. 2901-02).

2852. [REDACTED] (Fiedler (FMI) Tr. 4498 (*in camera*)).

2853. In its annual report, Natera expressed, “Illumina is currently the sole supplier of our sequencers and related reagents for [our tests]. . . . Without sequencers and the related reagents, we would be unable to run our tests and commercialize our products.” (PX0155 at 39 (Natera 10-K, Feb. 25, 2021)).

2854. In its annual report, Natera acknowledged that Illumina’s acquisition of Grail might add to the risks associated with Illumina being its sole supplier of sequencers and reagents. (PX0155 at 40 (Natera 10-K, Feb. 25, 2021)).

(3) MCED Customers Rely on Illumina for Assistance, Service, and Support of Illumina’s NGS Products

2855. [REDACTED]  
[REDACTED] (Conroy (Exact) Tr. 1583-84 (*in camera*)).

2856. [REDACTED]  
[REDACTED] } (Conroy (Exact) Tr. 1583-84 (*in camera*)).

2857. Pre-Acquisition, when there was an issue with a customer’s purchase or supply, Illumina claims to “do our best to resolve customer issues quickly.” (PX7076 (Berry (Illumina) Dep. at 83-84)).

2858. Pre-Acquisition, Illumina tried to assist customers by making sure that products get to its customers when they want them. (PX7076 (Berry (Illumina) Dep. at 85-86); *see e.g.*, PX2601 (Illumina) at 002-004 (Email exchange between J. Gripp, Illumina, S. Verbeek, Illumina, T. Curti, Illumina, et al., Nov. 13, 2021) (*in camera*) ([REDACTED])).

2859. Mr. Getty testified that a portion of Guardant’s product “portfolio is dependent on Illumina and their sequencers and reagents, service.” (Getty (Guardant) Tr. 2517).

(a) *MCED Test Developers Testified that the Speed and Quality of Illumina’s Customer, Technical, Product Development, and Regulatory Support Can Alter the Quality, Development, and Delivery of Developers’ Products*

(i) *Illumina Testimony and Ordinary Course Documents Show that Illumina’s Customer, Technical, and Regulatory Support Can Alter the Speed, Quality, Development, and Delivery of Developers’ Products*

2860. Illumina’s service and support team installs Illumina’s equipment in customers’ laboratories. (Berry (Illumina) Tr. 646).

2861. Illumina services Illumina equipment that customers purchase. (Berry (Illumina) Tr. 646).

2862. Illumina provides customers with technical support to resolve any problems with Illumina products. (Berry (Illumina) Tr. 646).

2863. Illumina provides customers with field application scientists who administer “training to enable the customer to successfully use” Illumina instruments. (Berry (Illumina) Tr. 670).

2864. Illumina's field application scientists train customers after a customer purchases an Illumina instrument and subsequently upon a customer's request. (Berry (Illumina) Tr. 669-70).
2865. Illumina provides customers with field service engineers to perform routine maintenance and repair customers' instruments. (Berry (Illumina) Tr. 668-69).
2866. Illumina's Nicole Berry testified that Illumina's field service engineers service a customer's NovaSeq 6000 once a month on average. (Berry (Illumina) Tr. 675).
2867. Illumina provides customers with field service engineers to perform "break/fix service" when instruments experience a failure that prevents customers from operating the instruments. (Berry (Illumina) Tr. 668).
2868. [REDACTED] } (PX2378 (Illumina) at 003 (Illumina, Quote Approval Request, Dec. 27, 2018) (*in camera*); Berry (Illumina) Tr. 682-83).
2869. Ms. Berry testified that some Illumina customers have Illumina service engineers working full time at the customers' labs:

We have got some customers that are very large and with many, many, many instruments, and the economics and also just the practical reality of what it takes to support very large fleets lends itself oftentimes to not only an onsite but an onsite with multiple FTEs, or full-time equivalents, for -- to provide the labor.

(Berry (Illumina) Tr. 682-83).

2870. [REDACTED] } (*See, e.g.*, PX2598 (Illumina) at 002-003 (Email from D. Krebbel, Illumina, to D. Daly, Illumina, et al., Apr. 13, 2018) (*in camera*) ( [REDACTED] ); PX2602 (Illumina) at 009 (Email from T. Trinh, Illumina, to ILMN-Com-Instrument Service, Nov. 16, 2020) (*in camera*) ( [REDACTED] )); PX7063 (Berry (Illumina) IHT at 108-109) (*in camera*); PX7105 (Getty (Guardant) Dep. at 6)).
2871. Illumina's internal documents show that [REDACTED] } (*See, e.g.*, PX2599 (Illumina) at 003 (Email from L. Leigh, Illumina, to M. Gallina, Illumina, et al.,

Oct. 9, 2020) (*in camera*) [REDACTED] [REDACTED] }; PX2597 (Illumina) (Email from W. Caceres, Illumina, to E. Chen, Illumina, et al., Mar. 25, 2018) (discussing Illumina’s assistance with the installation of sequencers); PX2603 (Illumina) (Email from G. Nunn, Illumina, to L. Tonkin, Illumina, et al., May 11, 2016) (*in camera*) [REDACTED] [REDACTED] }.

(ii) *MCED Test Developers Testified that the Speed and Quality of Illumina’s Customer and Technical Support can Alter the Quality, Development, and Delivery of Developers’ Products*

2872. [REDACTED] [REDACTED] } (PX7105 (Getty (Guardant) Dep. at 55-56); PX2599 (Illumina) at 003 (Email from L. Leigh, Illumina, to M. Gallina, Illumina, et al., Oct. 9, 2020) (*in camera*); PX2597(Illumina) (Email from W. Caceres, Illumina, to E. Chen, Illumina, Mar. 25, 2018); PX2603 (Illumina) (Email from G. Nunn, Illumina, to L. Tonkin, Illumina, et al., May 11, 2016) (*in camera*)).
2873. MCED witnesses also testified that they rely on Illumina for service and support. (PX7105 (Getty (Guardant) Dep. at 61-62) (explaining that Guardant relies on Illumina for service and support on a daily basis). For example, Guardant relies upon Illumina to service its sequencers. (Getty (Guardant) Tr. 2509).
2874. Guardant relies on Illumina for servicing of machines, regulatory support, and the “development and finetuning of our technology.” (Getty (Guardant) Tr. 2509)
2875. Ms. Berry testified that when a customer orders “a new instrument... [Illumina] would provide normal assistance, you know, support,...installation of the instrument, customer training.” (PX7076 (Berry (Illumina) Dep. at 149)).
2876. Guardant’s Bill Getty testified that Illumina technicians come to Guardant’s lab to work on sequencers on a regular basis, probably weekly. (Getty (Guardant) Tr. 2514).
2877. Guardant relies on Illumina in its product development and the fine-tuning of Guardant’s technology. (Getty (Guardant) Tr. 2509, 2514).
2878. Mr. Getty explained that Illumina’s instruments are “highly tuned machines,” so “in order for us to maximize the value of those, we certainly need to know from Illumina representatives how those might be best deployed.” (Getty (Guardant) Tr. 2514).
2879. Mr. Getty explained that “without [Illumina’s] sequencers [and] without the service that Illumina provides to keep them in good working order, [Guardant] would be unable to run [blood samples of patients] and deliver the final product to patients.” (Getty (Guardant) Tr. 2685-86).

2880. “[T]here’s a symbiotic relationship between Guardant Health and our activity and Illumina’s activities in terms of making sure we’re maximizing the value of the products they have delivered to us.” (Getty (Guardant) Tr. 2509).

2881. [REDACTED]

2882. [REDACTED] (PX7094 (Nolan (Freenome) Dep. at 277-278) (*in camera*)).

2883. [REDACTED] } (PX7094 (Nolan (Freenome) Dep. at 277-278) (*in camera*)).

2884. [REDACTED] } (PX7094 (Nolan (Freenome) Dep. at 156-157) (*in camera*)).

2885. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 72) (*in camera*)).

2886. [REDACTED] } (Conroy (Exact) Tr. 1584 (*in camera*)).

2887. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 231 (*in camera*)).

2888. [REDACTED]

2889. [REDACTED]

2890. [REDACTED]

2891. [REDACTED]

(iii) *MCED Test Developers Testified that the Speed and Quality of Illumina's Product Development Support Can Alter the Quality, Development, and Delivery of Developers' Products*

2892. Guardant's Bill Getty explained that if Illumina were to slow down its service of Guardant's Illumina equipment, "[I]t may be so impactful that it would slow down our competitiveness in the marketplace such that we would, you know, not be a viable player in the market." (PX7105 (Getty (Guardant) Dep. at 62)).

2893. Mr. Getty testified that turnaround time "is one of the most important aspects and features of a test." (PX7105 (Getty (Guardant) Dep. at 63-64)). Mr. Getty stated bluntly, "cancer doesn't wait for us to, you know, get our machines fixed. The faster we can deliver that information, the more . . . valuable that information is. . . . [W]e know from many hours of market research that from a physician's standpoint, it's incredibly important." (PX7105 (Getty (Guardant) Dep. at 63-64)).

2894. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 72) (*in camera*)).

2895. [REDACTED] } (Chahine (Helio) Tr. 1074-75 (*in camera*)).

2896. [REDACTED] } (Conroy (Exact) Tr. 1583 (*in camera*)).

2897. [REDACTED] (Conroy (Exact) Tr. 1584 (*in camera*)).

2898. [REDACTED]

2899. [REDACTED]

2900. [REDACTED]

[REDACTED]

(b) *Like Rival MCED Test Developers, Grail Depends on Illumina for Pricing, Supply, Product Support, and Customer Assistance throughout the Product Lifecycle*

- 2901. As discussed in detail in Section V.D.2., MCED test developers, including Grail, are reliant upon Illumina NGS.
- 2902. Grail relies on Illumina as a sole supplier for next-generation sequencers and associated reagents. (Bishop (Grail) Tr. 1336; PX4082 (Grail) at 015 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).
- 2903. [REDACTED] (PX4016 (Grail) at 007 (GRAIL Strategy Planning Roadmap (Workshop #2) (Sept. 2, 2020)) (*in camera*)).
- 2904. [REDACTED] } (Freidin (Grail) Tr. 3065 (*in camera*)).
- 2905. [REDACTED] } (PX7066 (Freidin (Grail) IHT at 212-213 (*in camera*); PX6049 (Grail) at 023 [REDACTED] (*in camera*)).
- 2906. [REDACTED] (*in camera*)).
- 2907. [REDACTED] } (Freidin (Grail) Tr. 3065-66 (*in camera*)).
- 2908. Grail identified its reliance on Illumina as a risk factor in its Form S-1. (Bishop (Grail) Tr. 1335-36; PX4082 (Grail) at 015 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).
- 2909. In an internal email discussing attempts to reduce prices received from Illumina in connection with sequencing, Grail personnel described “cost per sequencing read [as] the most important.” (PX4019 (Grail) (Email from M. Chung, Grail, to J. Wong, Grail, Sept. 29, 2018)).
- 2910. In its SEC Form S-1, Grail identified risks that it would encounter from switching suppliers:

Transitioning to a new supplier for this equipment or these materials would be time-consuming and expensive, could result in interruptions in or otherwise



affect the performance specifications of our laboratory operations and sample processing or could require that we revalidate our products and, if we receive FDA clearance or approval for our products, could require a new submission to FDA and oilier regulatory bodies to approve or clear such changes.

(PX4082 (Grail) at 034 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).

2911. At trial, Mr. Bishop described the risks to Grail of switching suppliers, as stated in Grail’s Form S-1 (PX4082):

[O]ur understanding of the risks are as written in the sentence you’ve highlighted for us [in Grail’s Form S-1, PX4082]. Transitioning to a new supplier for the equipment or materials listed above could take time, could be expensive, could result in interruptions and, as it goes on to say, could require that we revalidate our products if we receive FDA clearance or approval for those products, so it’s speculating on a number of scenarios.

(Bishop (Grail) Tr. 1341).

2912. In its Form S-1, Grail identified “consistent source of supply” as a risk that could force Grail to alter its laboratory operations and test procedures: “[W]e purchase certain products on a purchase order basis and cannot guarantee a consistent source of supply. The use of equipment or materials provided by a replacement supplier could require us to alter our laboratory operations and sample collection and processing and related procedures.” (PX4082 (Grail) at 034 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).

2913. In its Form S-1, Grail expressed that a substitute to Illumina “may not be available at all”:

In the case of attempting to obtain an alternative supplier for Illumina, Streck, or Twist, replacement instruments and associated reagents, tubes, and panels that meet our quality control and performance requirements may not be available at all, or may not be available on reasonable terms or in a timely manner.

(PX4082 (Grail) at 034 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).

2914. In its Form S-1, Grail acknowledged, “Any disruption in Illumina’s operations or breach of our supply-related agreements would impact our supply chain and laboratory operations as well as our ability to develop and commercialize our products, including Galleri and DAC.” (PX5049 at 29 (Grail Form S-1, Sept. 9, 2020)).

2915. In its Form S-1, Grail described how delays or difficulties in its supply of equipment, reagents, and other required materials would likely affect the company:

If we encounter delays or difficulties in securing, reconfiguring, or revalidating the equipment, reagents, and other materials that we require for our laboratory operations and sample collection and processing, we would likely face significant delays in commercializing our products and our business, financial condition, results of operations, and growth prospects would be adversely affected.

(PX4082 (Grail) at 034 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et al., attaching Grail 2020 S-1/Amended, Sept. 2020)).

2916. In a presentation prepared for Grail’s Board of Directors by Morgan Stanley in connection with evaluating the potential acquisition by Illumina, Morgan Stanley included a slide titled “Key Risks to Stand Alone Value Realization.” On that slide, Morgan Stanley wrote that “[m]argin impact from supply agreement and royalties owed to [Illumina] may limit financial and strategic flexibility,” and referenced a “heavy reliance on Illumina’s products” in the “cancer genomics space.” (PX4148 (Grail) at 019 (Email from M. Song, Grail, to C. Friedman, et al., attaching Morgan Stanley, Discussion Materials: Project Valor, Sept. 14, 2020)).

2917. [REDACTED]  
(PX4618 (Grail) at 001-08 (Email from R. Huang, Grail, to Y. Hu, Grail, Apr. 29, 2021 (*in camera*))).

(4) Illumina Has the Ability to Disadvantage Grail’s Rivals by Reducing the Quality of Assistance, Service, and Support Provided to MCED Customers

2918. [REDACTED] } (Conroy (Exact) Tr. 1584 (*in camera*)).

2919. Guardant’s William Getty stated, “They [Illumina] could also, you know, one day turn around and, you know, say simple things like, you know, ‘We can’t get a technician out to your sequencers until next Friday’ or ‘the Friday after,’ and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively.” (PX7105 (Getty (Guardant) Dep. at 69-71)).

2920. [REDACTED] (Chudova (Guardant) Tr. 1229-30 (*in camera*)).

2921. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 72) (*in camera*)).

2922. [REDACTED] } (See, e.g., PX7051 (Lengauer (Third Rock Ventures) IHT at 93-94) (*in camera*)).

2923. [REDACTED] (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 69-71); PX7055 (Otte (Freenome) IHT at 108-109) (*in camera*)).

2924. [REDACTED] (See PX7110 (Conroy (Exact) Dep. at 72) (*in camera*); PX7105 (Getty (Guardant) Dep. at 69-71)).

2925. [REDACTED] (See PX2600 (Illumina) at 002 (Email from T. Trinh, Illumina, to E. Chen, Illumina, Feb. 12, 2020) (*in camera*) ([REDACTED]); PX2605 (Illumina) (Email from E. Chen, Illumina, to N. Kargozaran, Illumina, et al., Sept. 21, 2020 (*in camera*) ([REDACTED])).

2926. [REDACTED] } (PX2605 (Illumina) at 008 (Email from E. Chen, Illumina, to N. Kargozaran, Illumina, et al., Sept. 21, 2020 (*in camera*)).

2927. [REDACTED] (PX7110 (Conroy (Exact) Dep. at 72-73) (*in camera*)).

2928. [REDACTED] } (Fiedler (FMI) Tr. 4491-92 (*in camera*)).

2929. [REDACTED] (Fiedler (FMI) Tr. 4492 (*in camera*)).

2930. [REDACTED] } (Fiedler (FMI) Tr. 4492-93 (*in camera*)).

2931. [REDACTED] (Fiedler (FMI) Tr. 4493 (*in camera*)).

2932. [REDACTED] (PX8324 (Roche) at 005 (in camera)).

d) Illumina Can Deny Access to Information, Agreements, and Licenses Necessary for FDA Approval and Commercialization of MCED Tests

2933. As discussed in Section II.E.2. (FDA Approval Process), MCED tests will need FDA approval to gain broad reimbursement status and reach the broader MCED test market.

2934. As part of the FDA review process described in Section II.E.2. (FDA Approval Process), MCED test developers must provide substantial information and data to the FDA, including information related to the MCED test’s use of Illumina’s NGS platforms.

2935. In Section II.E.2. (FDA Approval Process), executives of MCED test developers, Illumina, and Grail testified that the FDA approval process is lengthy, complicated, difficult, and requires several submissions of details information and data.

2936. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 154-55) (in camera)).

2937. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 154-55) (in camera)).

2938. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 154-55) (in camera)).

2939. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 154-55) (in camera)).

2940. [REDACTED] (Conroy (Exact) Tr. 1587 (in camera); PX7110 (Conroy (Exact) Dep. 75-76) (in camera)).

2941. [REDACTED]

[REDACTED]

(Conroy (Exact) Tr. 1588 (*in camera*)).

2942. [REDACTED] }  
(PX7110 (Conroy (Exact) Dep. 76) (*in camera*)).

2943. [REDACTED] } (PX7110 (Conroy  
(Exact) Dep. 76) (*in camera*)).

2944. [REDACTED] } (PX7110 (Conroy  
(Exact) Dep. 73-74) (*in camera*)).

(1) MCED Test Developers Testified that a Distributed or Kitted Version of MCED Tests Are Part of Their Product Pipeline

2945. An IVD test developer may seek FDA approval for its test as a “single-site” IVD test, which can run at one approved lab, or as a “distributed” IVD test, which can run at any third-party lab. (*See* PX7063 (Berry (Illumina) IHT at 202); PX7112 (Bailey (PGDx) Dep. at 14); PX7093 (Young (Illumina) Dep. at 43-44)). A distributed or “kitted” IVD is an IVD test that has received PMA approval from the FDA permitting analysis by independent testing providers, such as hospitals or large reference labs like LabCorp or Quest. (Goswami (Illumina) Tr. 3186-87; Leite (Illumina) Tr. 2150; PX7049 (Bailey (PGDx) IHT at 68-69); PX7063 (Berry (Illumina) IHT at 202); PX7112 (Bailey (PGDx) Dep. at 14-18); PX7093 (Young (Illumina) Dep. at 44)).

2946. [REDACTED]

2947. [REDACTED]

[REDACTED] (PX7100)

2948. [REDACTED]

2949. [REDACTED]

2950. Singlera wants to offer the PanSeer test as a distributed test in order to differentiate it from single-site tests. (PX7042 (Gao (Singlera) IHT at 109) (“Q. Then switching back to the PanSeer, does Singlera plan to offer this, the PanSeer test, as a distributed IVD test? A. That’s our original thought. We want to differentiate from single-site licensing. We want to be a distributed mode. So our business model will be deliver the test in a distributed way so we can work with the partners.”)).

2951. Dr. Gao testified that selling the PanSeer test as a distributed test would allow Singlera to “quickly scale up to sell.” (PX7042 (Gao (Singlera) IHT at 110-11)).

2952. [REDACTED]

2953. [REDACTED]

2954. Distributed IVD tests allow samples to be processed locally, which improves turnaround time for test results and alleviates capacity constraints at developers’ centralized labs, which will likely be critical for test developers as MCEd tests become routinely used in the market. (PX7042 (Gao (Singlera) IHT at 110-11); PX7049 (Bailey (PGDx) IHT at 68-69)).

(2) For the FDA to Approve a Distributed or Kitted Version of an MCEd Test, the MCEd Test Developer Needs an IVD Agreement with Illumina and Illumina Must Provide More Detailed Information to the FDA on Behalf of the MCEd Test Developer

2955. A single-site PMA or a single-site IVD is an IVD test that has received PMA approval from the Food & Drug Administration (“FDA”) requiring sample analysis at a single designated facility. (Goswami (Illumina) Tr. 3186).

2956. A distributed kit (or “kitted”) in-vitro diagnostic is when the test developer generates a “kit” version of the test, which can then be distributed to other CLIA/CAP-certified labs to be processed. (Goswami (Illumina) Tr. 3186-88).
2957. A kitted IVD is an IVD test that has received PMA approval from the FDA permitting analysis by independent testing providers. (Goswami (Illumina) Tr. 3187).
2958. To develop a kitted version of an MCED test, the MCED test developer needs an IVD agreement with Illumina. (Goswami (Illumina) Tr. 3188-89; 3234-35)
2959. Illumina requires customers to enter into an IVD agreement to run a test on Illumina’s Dx instruments. (Goswami (Illumina) Tr. 3268).
2960. Illumina provides a device master file to the FDA when a kitted IVD test developer is seeking FDA approval. (Goswami (Illumina) Tr. 3224).
2961. When a kitted IVD test developer choses to develop its test on Illumina’s sequencers, Illumina learns the test developer’s development plans, when the developer will need the local run module for its test, when the developer plans to submit to the FDA for approval, and when the developer plans to commercialize its test. (Goswami (Illumina) Tr. 3226-27).
2962. Dr. Goswami testified that customers provide Illumina with volume information so that “Illumina can provide the right level of support and inventory.” (Goswami (Illumina) Tr. 3272).
2963. Guardant relies on Illumina to support interactions with the FDA. (Getty (Guardant) Tr. 2509).
2964. Guardant relies on Illumina to provide documentation relating to Illumina NGS that is necessary for Guardant to pursue FDA approval. (Getty (Guardant) Tr. 2515).
2965. Mr. Getty testified at trial that Guardant “would need to work with Illumina” in order to obtain FDA approval to sell Guardant’s MCED test as a distributed IVD test. (Getty (Guardant) Tr. 2689).
2966. [REDACTED]  
[REDACTED] (PX7040 (Getty (Guardant) IHT at 86) (*in camera*)).
2967. [REDACTED]  
[REDACTED] (PX7040 (Getty (Guardant) IHT at 85-86) (*in camera*)).
2968. [REDACTED]  
[REDACTED]

(PX7040 (Getty (Guardant) IHT at 88) (in camera)). [REDACTED]

[REDACTED]

(PX7040 (Getty (Guardant) IHT at 88) (in camera)).

2969. [REDACTED].

2970. [REDACTED] (PX7075 (Stahl (Invitae) Dep. at 59-60) (in camera)).

2971. [REDACTED]

(PX7049 (Bailey (PGDx) IHT at 42-43) (in camera)).

2972. [REDACTED] (PX7063 (Berry (Illumina) IHT at 95) (in camera)).

2973. Illumina provides a device master file to the FDA when a kitted IVD test developer is seeking FDA approval. (Goswami (Illumina) Tr. 3224).

2974. [REDACTED] (Conroy (Exact) Tr. 1587 (in camera)). [REDACTED] (Conroy (Exact) Tr. 1587 (in camera)).



2975. [REDACTED] (PX7110 (Conroy (Exact) Dep. at 78) (*in camera*)).

2976. [REDACTED] (Conroy (Exact) Tr. 1589 (*in camera*)).

2977. [REDACTED] } (Conroy (Exact) Tr. 1591 (*in camera*)).

(3) To Run an FDA-Approved Distributed MCED Test, Third-Party Labs Must Have the Corresponding Illumina Dx Instrument Enabled and Supported by Illumina

2978. A test developer needs an IVD agreement with Illumina to distribute its test to third-party labs. (Goswami (Illumina) Tr. 3261-62).

2979. If an MCED test developer wants to offer its MCED test as an FDA-approved distributed kit, the third-party labs that run the test would need access to the NGS instrument approved for use with the kit and license to operate the instrument in the diagnostic (“Dx”) mode specified in the FDA’s approval. (PX7045 (Chudova (Guardant) Dep. at 81-83)).

2980. For kitted IVDs, Illumina makes a one-time “local run module,” which provides a software module to the test developer for reading the genetic output from the Illumina platform. (Goswami (Illumina) Tr. 3189).

2981. The test developer incorporates the local run module and can then distribute the module as part of its kitted IVD. (Goswami (Illumina) Tr. 3189).

2982. Guardant’s Dr. Chudova testified that to initiate a sequencing run on an Illumina Dx instrument, Guardant needs Illumina’s help:

[I]n order for [Guardant] to initiate a sequencing run on the Dx instrument using a particular sequencing protocol, we would need that enabled by Illumina on the Dx box, so whether it exists in [Guardant’s] lab or in partners’ labs, [Illumina] would need to enable access to the protocol to run Guardant 360 liquid biopsy . . . [a]nd unless they do it, customer cannot turn it on their own on the diagnostic box, right. It’s a locked device that has a particular configuration.

(PX7045 (Chudova (Guardant) Dep. at 89)).

2983. [REDACTED]



2989. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 197-98 (*in camera*)).

2990. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 196-99 (*in camera*)).

2991. [REDACTED] (PX7051 (Lengauer (Third Rock Ventures) IHT at 92-93, 189-91) (*in camera*)).

2992. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 197-98 (*in camera*)).

2993. [REDACTED] (Lengauer (Third Rock Ventures) Tr. 200 (*in camera*)).

2994. [REDACTED] }  
[REDACTED]  
(Lengauer (Third Rock Ventures) Tr. 200 (*in camera*)).

2995. [REDACTED] (Fiedler (FMI) Tr. 4494 (*in camera*)).

2996. [REDACTED] (Fiedler (FMI) Tr. 4493 (*in camera*)).

2997. [REDACTED]

[REDACTED] } (PX7068 (Perettie (FMI-Roche) IHT at 97) (*in camera*)).

f) Illumina Can Share the Competitively Sensitive Information of MCED Test Developers with Grail

(1) MCED Test Developers Share Competitively Sensitive Information with Illumina

- 2998. Illumina has access to a variety of sources and means to collect information about MCED test developers. (*See supra* Section VII.A.1 (Illumina Has the Ability to Identify and Discriminate Against MCED Test Developers Posing Competitive Threats to Grail’s Galleri Test and the Tools to Foreclose or Reduce the Competitiveness of Grails’ Rivals).
- 2999. Illumina learns several types of information from its IVD customers. (Goswami (Illumina) Tr. 3226-27). For example, Illumina learns about its customer’s development plans, when a customer will need the local run module for its test, when the customer plans to seek FDA approval, and when the customer plans to commercialize its test. (Goswami (Illumina) Tr. 3226-27).
- 3000. Illumina’s Dr. Goswami testified that customers provide Illumina with volume information so that “Illumina can provide the right level of support and inventory.” (Goswami (Illumina) Tr. 3272).
- 3001. When Illumina enters into supply agreements with customers, Illumina encourages customers to provide “some insight and visibility into what their future needs are.” (Berry (Illumina) Tr. 662-63).
- 3002. The information that customers usually provide to Illumina includes the anticipated frequency and quantity of shipments and mix of product purchases. (Berry (Illumina) Tr. 663).
- 3003. If customers do not provide forecast information to Illumina, then Illumina uses customers’ historical purchases to create customer forecasts. (Berry (Illumina) Tr. 662-63).
- 3004. Some customers’ sequencers connect to Illumina online allowing Illumina to monitor the instrument. (deSouza (Illumina) Tr. 2384-85).
- 3005. Some customers’ sequencers connect to Illumina via the internet to monitor the instrument or connect to Illumina’s cloud-based data storage service. (deSouza (Illumina) Tr. 2383-85).
- 3006. A customer can choose to send only instrumentation metrics—how the instrument is performing—or instrumentation metrics and the underlying genomic data to Illumina’s cloud-based storage service. (deSouza (Illumina) Tr. 2384-85).
- 3007. [REDACTED]

3008.

[REDACTED]

3009.

[REDACTED]

3010.

[REDACTED]

3011.

[REDACTED]

3012.

[REDACTED]

3013.

[REDACTED]

3014.

[REDACTED]

3015.

[REDACTED]

3016.

[REDACTED]

3017.

[REDACTED]

3018. [REDACTED]

3019. [REDACTED]

3020. [REDACTED]

3021. [REDACTED]

3022. [REDACTED]

(2) No Firewall Can Prevent Disclosure of Competitively Sensitive Material

3023. Section 10(b) of the Open Offer provides for the establishment of a firewall to prevent Grail from accessing any “confidential information” that other Illumina customers provide to Illumina. (Berry (Illumina) Tr. 716).

3024. Illumina’s Nicole Berry testified that the Open Offer does not define what constitutes confidential information. (Berry (Illumina) Tr. 716-18).

3025. As described in detail in Section VIII.A.3.j. (Illumina’s Commitments to Confidentiality Are Flawed), MCED test developers testified that Illumina’s Open Offer firewall provision is insufficient to prevent the sharing of their competitively sensitive information between Illumina and Grail.

3026. [REDACTED] (PX7109 (Daly (Singular Genomics) Dep. at 54-59) (*in camera*)).

3027. [REDACTED] } (PX7110 (Conroy (Exact) Dep. 248-49) (*in camera*)).
3028. [REDACTED] } (Getty (Guardant) Tr. 2557 (*in camera*)).
3029. [REDACTED] (Getty (Guardant) Tr. 2559 (*in camera*)).
3030. [REDACTED] } (Getty (Guardant) Tr. 2559 (*in camera*)).
3031. [REDACTED] } (Rabinowitz (Natera) Tr. 373 (*in camera*)).
3032. [REDACTED] } (deSouza (Illumina) Tr. 2280-81 (*in camera*)).
3033. [REDACTED] } (deSouza (Illumina) Tr. 2281 (*in camera*)).
3034. [REDACTED] (deSouza (Illumina) Tr. 2281 (*in camera*)). [REDACTED] } (deSouza (Illumina) Tr. 2281 (*in camera*)).
3035. [REDACTED] } (deSouza (Illumina) Tr. 228182 (*in camera*)).
3036. Grail’s new CEO is Illumina veteran Bob Ragusa, who served as Illumina COO prior to this appointment and worked at Illumina since 2013. (PX0405 (Press Release, Illumina Appoints Bob Ragusa as Chief Executive Officer (CEO) of GRAIL, Oct. 14, 2021)). As of September 2020, Ragusa holds about \$1 million in Illumina stock. (PX4619 (Grail) at 187, 197 (Email from V. Korobkin, Morgan Stanley, to M. Podoll, Morgan Stanley, et al., attaching “Public Information Book: Watson,” Sept. 12, 2020)).
3037. [REDACTED] } (PX6056 (Illumina) at 038-043 (Illumina, Narrative Responses of Illumina, Inc. to the Second Request for Additional Information and Documentary Material Issued by the Federal Trade Commission on November 9, 2020, Mar. 1, 2021) (*in camera*)).

- 3038. [REDACTED] } (deSouza (Illumina) Tr. 2282 (*in camera*)).
- 3039. [REDACTED] } (deSouza (Illumina) Tr. 2282 (*in camera*)).
- 3040. [REDACTED] } (deSouza (Illumina) Tr. 2282 (*in camera*)).
- 3041. [REDACTED] } (deSouza (Illumina) Tr. 2282 (*in camera*)).
- 3042. [REDACTED] } (deSouza (Illumina) Tr. 2282 (*in camera*)).
- 3043. [REDACTED] } (deSouza (Illumina) Tr. 2284 (*in camera*)).
- 3044. [REDACTED] } (deSouza (Illumina) Tr. 2283-84 (*in camera*)).
- 3045. [REDACTED] (deSouza (Illumina) Tr. 2284-85 (*in camera*)).
- 3046. [REDACTED] (deSouza (Illumina) Tr. 2285 (*in camera*)).
- 3047. [REDACTED] } (deSouza (Illumina) Tr. 2285-86 (*in camera*)).
- 3048. [REDACTED] } (deSouza (Illumina) Tr. 2286 (*in camera*)).
- 3049. [REDACTED] } (deSouza (Illumina) Tr. 2286 (*in camera*)).
- 3050. [REDACTED] } (deSouza (Illumina) Tr. 2286 (*in camera*)).
- 3051. [REDACTED] } (deSouza (Illumina) Tr. 2286 (*in camera*)).
- 3052. [REDACTED] (deSouza (Illumina) Tr. 2286 (*in camera*)).
- 3053. [REDACTED] } (deSouza (Illumina) Tr. 2286 (*in camera*)).



- 3054. [REDACTED] } (deSouza (Illumina) Tr. 2286-87 (*in camera*)).
- 3055. [REDACTED] (deSouza (Illumina) Tr. 2287 (*in camera*)).
- 3056. [REDACTED] } (deSouza (Illumina) Tr. 2287 (*in camera*)).
- 3057. [REDACTED] } (deSouza (Illumina) Tr. 2287 (*in camera*)).
- 3058. [REDACTED] (deSouza (Illumina) Tr. 2287 (*in camera*)).
- 3059. [REDACTED] } (deSouza (Illumina) Tr. 2287-2288 (*in camera*)).
- 3060. [REDACTED] (deSouza (Illumina) Tr. 2288 (*in camera*)).
- 3061. [REDACTED] } (deSouza (Illumina) Tr. 2287 (*in camera*)). [REDACTED] } (deSouza (Illumina) Tr. 2288 (*in camera*)).
- 3062. [REDACTED] } (deSouza (Illumina) Tr. 2288 (*in camera*)).
- 3063. [REDACTED] } (deSouza (Illumina) Tr. 2288 (*in camera*)).
- 3064. [REDACTED] } (deSouza (Illumina) Tr. 2288-2289 (*in camera*)).
- 3065. [REDACTED] } (deSouza (Illumina) Tr. 2289 (*in camera*)).
- 3066. [REDACTED] } (deSouza (Illumina) Tr. 2289 (*in camera*)).

g) Illumina Can Control IP Access and Sue for Application-Specific IP Infringement

3067. When analyzing potential acquisitions, Illumina internally favored markets where it could use IP as a “blocking mechanism to protect the profitability of the diagnostic market.” (PX2056 (Illumina) at 001 (Email from R. Chambers, Illumina, to N. Naclerio, Illumina, Nov. 17, 2015)).

3068. Michael Nolan, CEO of Freenome, testified that } [REDACTED]  
[REDACTED] (Nolan  
(Freenome) Tr. 2783-84 (*in camera*)).

3069. [REDACTED]  
[REDACTED] (Nolan (Freenome) Tr. 2783-84 (*in camera*)).

3070. [REDACTED]  
[REDACTED] (Nolan (Freenome) Tr. 2781 (*in camera*)).

3071. [REDACTED]  
[REDACTED] (Nolan  
(Freenome) Tr. 2781 (*in camera*)).

3072. [REDACTED]  
[REDACTED] } (Nolan (Freenome) Tr. 2781 (*in camera*)).

3073. Mr. Nolan explained that Freenome wants to have } [REDACTED]  
[REDACTED] (Nolan (Freenome) Tr. 2784 (*in camera*)).

3074. Mr. Nolan testified that Freenome wants } [REDACTED]  
[REDACTED] (Nolan (Freenome) Tr. 2784 (*in camera*)).

3075. [REDACTED]  
[REDACTED] (PX8324 (Roche) at 003  
(*in camera*)).

3076. [REDACTED]  
[REDACTED] (PX8324 (Roche) at 007  
(*in camera*)).

3077. [REDACTED]



(PX8324 (Roche) at 007 [redacted] (in camera) (emphasis in original).

3078.

[redacted] (PX8324 (Roche) at 007 [redacted] (in camera)).

For additional evidence on how Illumina has used intellectual property to inhibit its clinical competitors, see Section VII.D.3. (Illumina Identified and Used Similar Tools in the NIPT Market).

**B. ILLUMINA HAS THE INCENTIVE TO LESSEN COMPETITION IN THE U.S. MCED TEST MARKET BY DISADVANTAGING GRAIL’S RIVALS**

3079. Vicky Demas, Grail’s Platform Product Manager and New Products Program Lead, informed Grail CEO Hans Bishop and Grail’s Executive Leadership Team that “GRAIL’s acquisition by Illumina was a question to many of our competitors and to Illumina itself” at a September 2020 industry conference, and that “the focus was on [I]llumina as a platform provider and how those relationships might change.” (PX4005 (Grail) at 001 (Email from V. Demas, Grail, to Grail’s Executive Leadership Team, et al., September 28, 2020)).

3080. In 2015, Illumina’s CEO at the time, Jay Flatley, sent Francis deSouza “Final Notes” from a Board Strategic Offsite that describe the vision for Illumina’s “Org and Culture” as follows:

“May God have mercy on my enemies, because I will not!”

(PX2358 (Illumina) at 005 (Email from J. Flatley, Illumina, to F. deSouza, Illumina, attaching “Final Notes – 2015 Board Strategic Offsite,” Nov. 9, 2015) (further advocating for “violent[] execut[ion]” of corporate plans)).

**1. A Combined ILMN-Grail Has the Incentive to Maximize Firmwide Profits**

a) Pre-Merger, ILMN Had the Incentive to Promote Innovation and Multiple MCED Tests

3081. Dr. Fiona Scott Morton explained:

[REDACTED]

(PX6090 (Scott Morton Report) ¶ 165 (*in camera*)).

3082.

[REDACTED] *see also* PX4291 (Grail) [REDACTED] (*in camera*) [REDACTED] ).

3083. Illumina stated in internal Q&A bullets that that divesting Grail would “accelerate the liquid biopsy market for all.” (PX2406 (Illumina) at 005 (Email from J. Flatley, Illumina, to E. Endicott et al., Illumina, attaching Illumina/Grail Q&A, Jan. 2, 2017).

3084. Following Illumina’s spinoff of Grail in 2017, Francis deSouza stated publicly:

There are 70-plus players now in the liquid biopsy space. We want to encourage them to look at all different avenues because this is important and the outcome’s terrific for mankind. There are different points of view. There are companies that believe it’s going to be a combination of ultra-deep screening of the blood samples plus tissue, whole transcriptome analysis to identify tissue of origin. And to be honest, I think people are approaching it slightly differently and the market will sort of determine where the biology is and what the right answer is. In every case though, we’re talking about a lot of sequencing.

(PX0376 at 007 (Illumina Inc. at Goldman Sachs Global Healthcare Conference Call Transcript, June 13, 2017).

3085. At the same conference, deSouza stated of the liquid biopsy market: “[W]e want to encourage that market because that market, I think, is very promising from a patient perspective, but it uses a lot of sequencing.” (PX0376 at 007 (Illumina Inc. at Goldman Sachs Global Healthcare Conference, FD (Fair Disclosure) Wire, Conference Call Transcript, June 13, 2017).

3086. In a 2017 presentation to Sands Capital Management, Illumina told investors “We spun out Grail to encourage investment into many different NGS-based companies focused on early cancer detection to have as many shots on goal as possible.” (PX2561 (Illumina) at 017 (Email from J. Cunningham, Illumina, to F. deSouza, Illumina, attaching “DRAFT Sands Investor Talking Points,” Oct. 30, 2020); deSouza (Illumina) Tr. 2204-5).

3087. Dr. Scott Morton explained that [REDACTED] (PX6090 (Scott Morton Report) ¶ 165 (*in camera*)). Dr. Scott Morton concluded: [REDACTED]

[REDACTED] (PX6090 (Scott Morton Report) ¶ 165 (*in camera*)).

3088. With respect to the pricing of Illumina’s products, Dr. Scott Morton concluded that: [REDACTED] } (PX6090 (Scott Morton Report) ¶ 166 (*in camera*)).

3089. [REDACTED] (PX7138 (Scott Morton, Trial Dep. at 54-55) (*in camera*)).

3090. [REDACTED] } (PX7138 (Scott Morton, Trial Dep. at 57) (*in camera*)).

3091. [REDACTED] (PX6090 (Scott Morton Report) ¶ 171 (*in camera*)).

3092. [REDACTED] (PX6090 (Scott Morton Report) ¶ 166 (*in camera*)).

3093. [REDACTED]

[REDACTED]

[REDACTED] }

(PX6090 (Scott Morton Report) ¶ 167-68 (*in camera*)).

3094. When acquiring Grail, deSouza told Illumina’s investors that the Acquisition will create more value to Illumina’s shareholders than simply selling instruments and reagents to Grail. (deSouza (Illumina) Tr. 2220).

3095. [REDACTED] } (PX6090 (Scott Morton Report) ¶ 168 (*in camera*)).

b) Post-Merger, ILMN Has the Financial Incentive to Maximize the Combined Profits of ILMN and Grail

3096. [REDACTED] } (PX5030 (Illumina) at 009 (*in camera*)); PX7059 (Scagnetti (Illumina) IHT at 67-68) (*in camera*)).

3097. [REDACTED] (PX2150 (Illumina) at 001 [REDACTED] (*in camera*)).

3098. Dr. Carlton stated that the amount of downstream diversion is an important factor in determining the likely effects of the transaction. (PX7134 (Carlton Dep. at 152-53).

3099. [REDACTED] (See PX7138 (Scott Morton Trial Dep. at 248-49) (*in camera*)). [REDACTED]

[REDACTED]

(PX6090 (Scott Morton Report) ¶ 268) (*in camera*)).

3100. [REDACTED] } (PX6090 (Scott Morton Report) ¶ 171 (*in camera*)).

3101. [REDACTED] (PX6090 (Scott Morton Report) ¶ 171 (*in camera*)).

3102. [REDACTED]

[REDACTED]

[REDACTED]

(PX6090 (Scott Morton Report) ¶ 171 (*in camera*)).

3103. [REDACTED] (PX8324 (Roche) at 003 [REDACTED] (*in camera*)).

3104. [REDACTED] (PX6090 (Scott Morton Report) ¶ 171 (*in camera*)).

3105. When deciding whether to approve Illumina's acquisition of Grail, Illumina's Board of Directors considered [REDACTED] . (PX2549 (Illumina) at 032 (Board of Directors Meeting (Virtual), Apr. 28, 2020) (*in camera*)).

3106. When Illumina considered whether to acquire Grail, Illumina understood that [REDACTED] . (PX2549 (Illumina) at 032 (Board of Directors Meeting (Virtual), Apr. 28, 2020) (*in camera*)).

**2. Potential Profits of MCED Tests Far Outweigh Profits from NGS Sales**

3107. As discussed below, internal Illumina documents from fall 2020 reflect a growing realization that [REDACTED] [REDACTED] (PX2169 (Illumina) at 045 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)); PX2488 (Illumina) at 008 [REDACTED] (*in camera*)).

3108. Illumina’s internal projections forecast revenues from its NGS instruments and core consumables to grow from [REDACTED] [REDACTED] (PX2488 (Illumina) at 008 [REDACTED] (*in camera*)).

3109. Illumina’s internal analysis presented to the Board of Directors stated that [REDACTED] [REDACTED] (PX2488 (Illumina) at 008 [REDACTED] (*in camera*)); PX2465 (Illumina) at 007 [REDACTED] (*in camera*); PX2169 (Illumina) at 042 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).

3110. Illumina’s CEO, Francis deSouza, testified at trial that he expects a decline in the profit pools associated with sequencers. (deSouza (Illumina) Tr. 2385).

3111. Mr. deSouza testified at trial that Illumina’s “core business is to sell sequencers and consumables. That’s how we make the vast majority of our revenue.” (deSouza (Illumina) Tr. 2378).

a) Illumina’s Documents and Market Participants Project Massive Revenue and Profit from the MCED Testing Market

3112. In its internal documents, Illumina recognizes that [REDACTED] [REDACTED] (PX2151 (Illumina) at 005 (Email from J. Cunningham, Illumina, to S. Samad, Illumina, attaching “Sands Capital Management Call,” Oct. 11, 2020)). See (PX2035 (Illumina) at 002 (Illumina, Oncology Testing 5-Year Strategy Refresh) (*in camera*) (explaining that [REDACTED] [REDACTED] )); PX2316 (Illumina) at 023 (Email from J. Goswami, Illumina, to A. Qadan et al., Illumina, attaching “Board of Directors M&A Landscape,” Apr. 29, 2020) (*in camera*) (estimating that [REDACTED] [REDACTED] ))).



3113. In a board presentation, Illumina’s SVP of Corporate Development & Strategic Planning, Joydeep Goswami, { [REDACTED] } (PX2316 (Illumina) at 008 (Email from J. Goswami, Illumina, to A. Qadan et al., Illumina, attaching “Board of Directors M&A Landscape,” Apr. 29, 2020) (*in camera*)); PX7087 (Goswami (Illumina) Dep. at 94-96) (discussing PX2316)(*in camera*)).
3114. Illumina’s 2021-2025 Strategic Plan { [REDACTED] } (PX2169 (Illumina) at 038 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).
3115. Illumina’s 2021-2025 Strategic Plan stated that { [REDACTED] } (PX2169 (Illumina) at 041 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*) { [REDACTED] }).
3116. Illumina’s 2021-2025 Strategic Plan concluded, { [REDACTED] } (PX2169 (Illumina) at 042 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).
3117. Illumina’s 2021-2025 Strategic Plan noted, { [REDACTED] } (PX2169 (Illumina) at 042 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (*in camera*)).
3118. A presentation to Illumina’s Audit Committee stated that { [REDACTED] } (PX2465 (Illumina) at 006 (*in camera*)).
3119. A presentation to Illumina’s Board of Directors { [REDACTED] } (PX2488 (Illumina) at 003 (*in camera*)).
3120. Illumina sought to { [REDACTED] } (PX2169 (Illumina) at 045

(Illumina Strategic Plan 2021-2025, Board Discussion Document,” Oct. 23, 2020) (*in camera*)).

3121. [REDACTED] } (PX2465 (Illumina) at 006-008  
[REDACTED] (*in camera*); PX2488 (Illumina) at 007-009  
(*in camera*)).

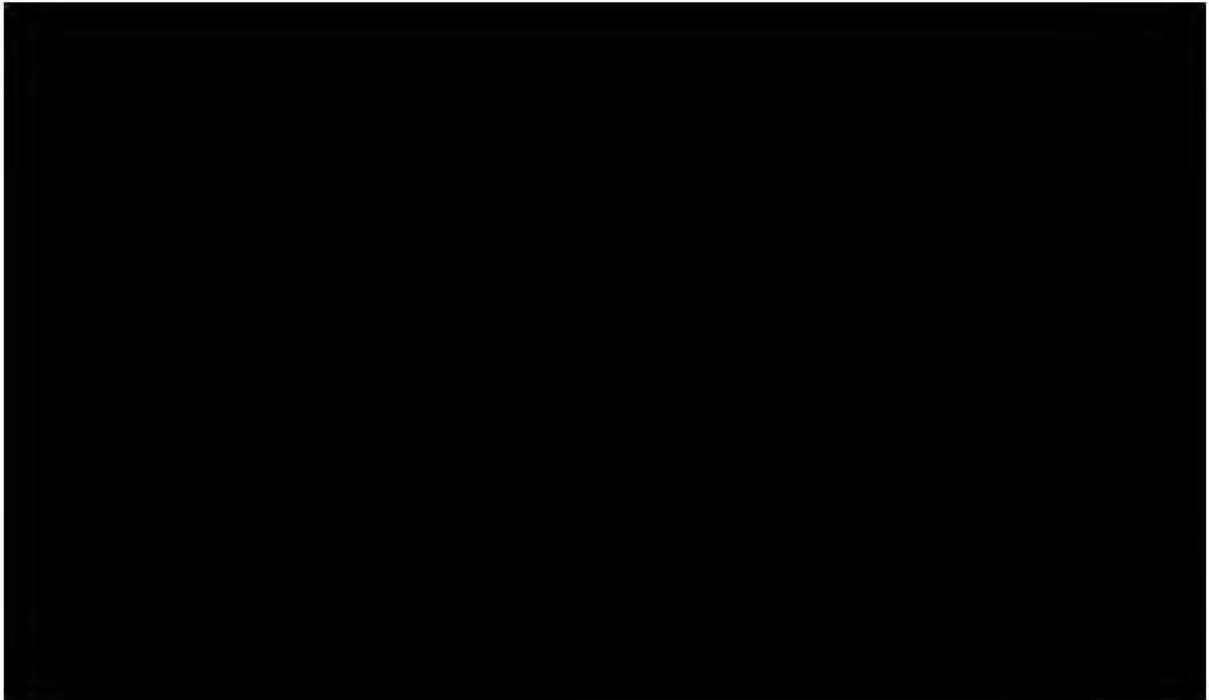
3122. [REDACTED] (PX2488  
(Illumina) at 008  
[REDACTED] (*in camera*)).

3123. In Illumina’s presentation to the Board of Directors [REDACTED]  
[REDACTED] (PX2488 (Illumina) at 007  
[REDACTED] (*in camera*)).

3124. [REDACTED] } (PX2488 (Illumina) at 008  
(*in camera*)).

3125. [REDACTED] } (PX2488 (Illumina) at 008  
[REDACTED] (*in camera*)  
[REDACTED] }.

3126. [REDACTED] (PX2488  
[REDACTED] (*in camera*)).



{ }

3127. Illumina's internal analysis recognized that [REDACTED] (PX2488 (Illumina) at 009 (in camera)). But the analysis warned that [REDACTED] (PX2488 (Illumina) at 009 (in camera)).

3128. In a presentation to Illumina's Board of Directors, Illumina [REDACTED] (PX2488

(Illumina) at 012 [REDACTED] (in camera).

3129. Therefore, Illumina predicted that [REDACTED] (PX2488 (Illumina) at 009 (in camera) (see image inset below); PX2465 (Illumina) at 008 (in camera); PX2169 (Illumina) at 043 (Illumina Strategic Plan 2021-2025, Board Discussion Document, Oct. 23, 2020) (in camera)).





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3130. In a presentation to Illumina’s Board of Directors, Illumina estimated that [REDACTED] (PX2488 (Illumina) at 003 (in camera)).


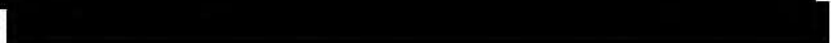
3131. In this presentation to Illumina’s Board of Directors [REDACTED] (PX2488 (Illumina) at 003 (in camera)); see also (PX2465 (Illumina) at 003 [REDACTED])

- [REDACTED] (in camera)).
3132. Further, in this presentation to Illumina’s Board of Directors, a [REDACTED] (PX2488 (Illumina) at 011) (in camera)).
3133. [REDACTED] (PX2488 (Illumina) at 011) (in camera)); see also (PX2465 (Illumina) at 009) (in camera)).
3134. [REDACTED] (PX5030 (Illumina) at 021) (in camera)).
3135. Illumina’s former CEO and Board Chairman, Jay Flatley, testified that Illumina forecasted that, in the long run, its revenue and profits would be greater through the acquisition of Grail compared to a smaller ownership stake. (Flatley (Illumina) Tr. 4096-97; PX2575 (Illumina) at 003 (Illumina, GRAIL Announcement Q&A, Sept. 20, 2020)).
3136. Illumina’s CEO, Francis de Souza, publicly stated in an investor call in September 2020 that the MCED market represents up to a \$60 billion incremental opportunity: “[s]pecifically, the acquisition positions Illumina to participate in what we expect will be a \$75 billion market for NGS-based oncology tests by 2035, \$60 billion higher than our oncology TAM [total addressable market] excluding GRAIL.” (PX2575 (Illumina) at 069 (Illumina, Investor Call Transcript, Sept. 21, 2020); see also (PX2031 (Illumina) at 003 (Illumina, Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 24, 2020) (stating that Illumina has “been moving into select clinical applications, and this acquisition adds the largest genomics application to our portfolio – and with it, an incremental \$60B TAM”)).
3137. Mr. deSouza told investors that the “early detection of cancer segment is the largest segment in the clinical market we can see for the next decade.” (PX2575 (Illumina) at 060 (Illumina, Illumina Inc at Cowen Liquid Biopsy Summit (Virtual), Sept. 24, 2020)); PX2151 (Illumina) at 005 (Illumina, Sands Capital Management Call, Oct. 11, 2020)

(stating that “[e]arly cancer detection is the largest opportunity in clinical genomics in our lifetime representing an incremental \$60B market opportunity by 2035.”)).

3138. Mr. deSouza told investors, “Direct participation ensures that our revenue share of these high value clinical applications will be higher than it would be if we are limited to supplying the hardware and consumables only. In short, Illumina’s revenue reflects clinical value, not simply the underlying sequencing output.” (PX2575 (Illumina) at 016 (Illumina, Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 23, 2020)). At trial, Mr. deSouza acknowledged that “by participating directly in that segment with our own solution, it allows Illumina to get a larger percentage of the value created in that solution rather than just being the platform provider.” (deSouza (Illumina) Tr. 2219) (referring to PX2575 (Illumina) at 060)).
3139. In a discussion at the Cowen Liquid Biopsy Summit, Francis deSouza stated that “the Grail acquisition gives [Illumina] a leading position in this very large market opportunity. And the early detection cancer market dwarfs the clinical markets we see today, NIPT and therapy selection for oncology combined.” (deSouza (Illumina) Tr. 2218-19 (referring to PX2575 (Illumina) at 060); see PX2564 (Illumina) at 005 (Email from J. Ross, Illumina, to F. deSouza, Illumina, Sept. 5, 2020 attaching Draft Project Valor Script) (“[W]e believe that the screening opportunity dwarfs therapy selection and monitoring.”)). Mr. deSouza acknowledged at trial that he was talking about the market opportunity that the Grail acquisition provided. (deSouza (Illumina) Tr. 2219).
3140. In representations to investors, Illumina’s CEO Mr. deSouza has acknowledged that MCED customers account for “roughly 2% of [Illumina’s] total revenue” and are aware of “maybe 20 out of [its] 6,600 customers who are targeting a commercial screening test.” (deSouza (Illumina) Tr. 2221-22) (referring to PX2575 (Illumina) at 018 (Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 23, 2020); PX2031 (Illumina) at 002 (Cowen Liquid Biopsy Summit with Francis deSouza, Sept. 24, 2020). Illumina included Guardant, Thrive, Freenome, Singlera, Exact, and Grail as early cancer screening companies. (deSouza (Illumina) Tr. 2221-2222).
3141.  (deSouza (Illumina) Tr. 2291 (*in camera*), 2382-83).
3142. In her expert report, Dr. Fiona Scott Morton concluded:  
  
 (PX6090 (Scott Morton Report) ¶ 201 (*in camera*)).

b) Market Participants Estimate That the MCED Market Will Grow to Be Significant

3143. At trial, Mr. Getty of Guardant estimated the potential size of the MCED market in terms of revenue as over \$50 billion. (Getty (Guardant) Tr. 2503).
3144. Guardant's MCED test will target 100 to 120 million average-risk individuals in the United States. (Getty (Guardant) Tr. 2501-02).
3145. Mr. Getty of Guardant projected that, on the low end, the MCED test market will reach \$50 billion: this is based on his estimation that the "market of a hundred million people and you look at the current cancer-screening modalities in the marketplace, take Cologuard as the exemplar, which has an average selling price of \$500, you quickly come to a conclusion of probably close to 50 billion dollars on the low end of things. If you're providing more value through multi-cancer, ostensibly you would have a higher price." (PX7105 (Getty (Guardant) Dep. at 50-51)).
3146.   
(PX8324 (Roche) at 012   
(*in camera*)).

3147. Singlera estimated that the global market for early-stage cancer screening is "expected to exceed" \$100 billion. (PX8515 (Singlera) at 004 (Singlera, Singlera Genomics)).

c) Third Parties Foresee Illumina's Changed Incentive as a Result of the Acquisition of Grail

3148. Several of Illumina's MCED test developer customers have expressed concerns about Illumina's incentives to favor Grail over its competitors post-merger. For example, Bill Getty, Guardant's Senior Vice President of Commercial, testified that Illumina's incentives will change as a result of acquiring Grail, "without question." (PX7040 (Getty (Guardant) IHT at 173)).
3149. On September 16, 2020, Rodger Currie, Grail's Senior VP of External Affairs, alerted Grail executives, including its CEO, Hans Bishop: "Thrive['s] SVP is now freaking out on me and wanting info [about the acquisition]. Obviously they feel this is not good for them. Which is entertaining." Currie added that it was "surely not a surprise to you to hear [Thrive is] freaking." (PX4021 (Grail) at 001 (Email from R. Currie, Grail, to H. Bishop, Grail, et al., Sept. 16, 2020)).

3150. Mr. Getty of Guardant explained: “there’s a much bigger market opportunity for Illumina as a screening company than there is as a sequencing company. . . . [T]herefore, you know, getting into [the cancer screening] business and controlling it through vertical integration of the technology underlying it, yeah, I mean, you would want to put us out of business, because ultimately they don’t compete with us in the sequencing business . . . . [b]ut we are certainly in the screening business, so, you know, by default, they want to push us out of that.” (PX7040 (Getty (Guardant) IHT at 173)).

3151. Guardant’s Mr. Getty testified, “the merger makes [Illumina] a player in this much bigger screening market, so they don’t need the customer of Guardant really anymore.” (PX7040 (Getty (Guardant) IHT at 173-74)).

3152. Mr. Getty explained that [REDACTED]  
[REDACTED]  
(PX7040 (Getty (Guardant) IHT at 173-74) (*in camera*)).

3153. But Mr. Getty warned,

[I]n the future, if they have access to this massive market, and that market is now, let’s say, a \$50 billion opportunity, and Grail can become a \$25-billion-a-year company based on that other screening market, well, guess what, [REDACTED]  
[REDACTED] } so why would you want to keep us happy at the same time and also have a competitor that splits that \$50 billion by another, you know, third or half. It just, you know, it -- it is completely in their best interest that we are not around.

(PX7040 (Getty (Guardant) IHT at 174-75) (*in camera*)).

3154. Mr. Getty of Guardant also explained that the “[t]he sequencing business is a much, much smaller slice . . . relative to that 60-billion-dollar opportunity. So as an organization, [Illumina’s] acquisition of Grail is ostensibly geared to moving into this much bigger opportunity and maximizing that opportunity.” (PX7105 (Getty (Guardant) Dep. at 68-69)).

3155. [REDACTED]  
[REDACTED]

3156. [REDACTED]  
[REDACTED]



3157. [REDACTED]

3158. [REDACTED]

3159. [REDACTED]

3160. [REDACTED]

3161. [REDACTED]

3162. [REDACTED]

3163. [REDACTED]

3164. [REDACTED]

3165. [REDACTED]

3166. [REDACTED]

3167. [REDACTED]

3168. [REDACTED]

3169. [REDACTED]

3170. [REDACTED]

3171. [REDACTED]

3172. [REDACTED]

3173. [REDACTED]

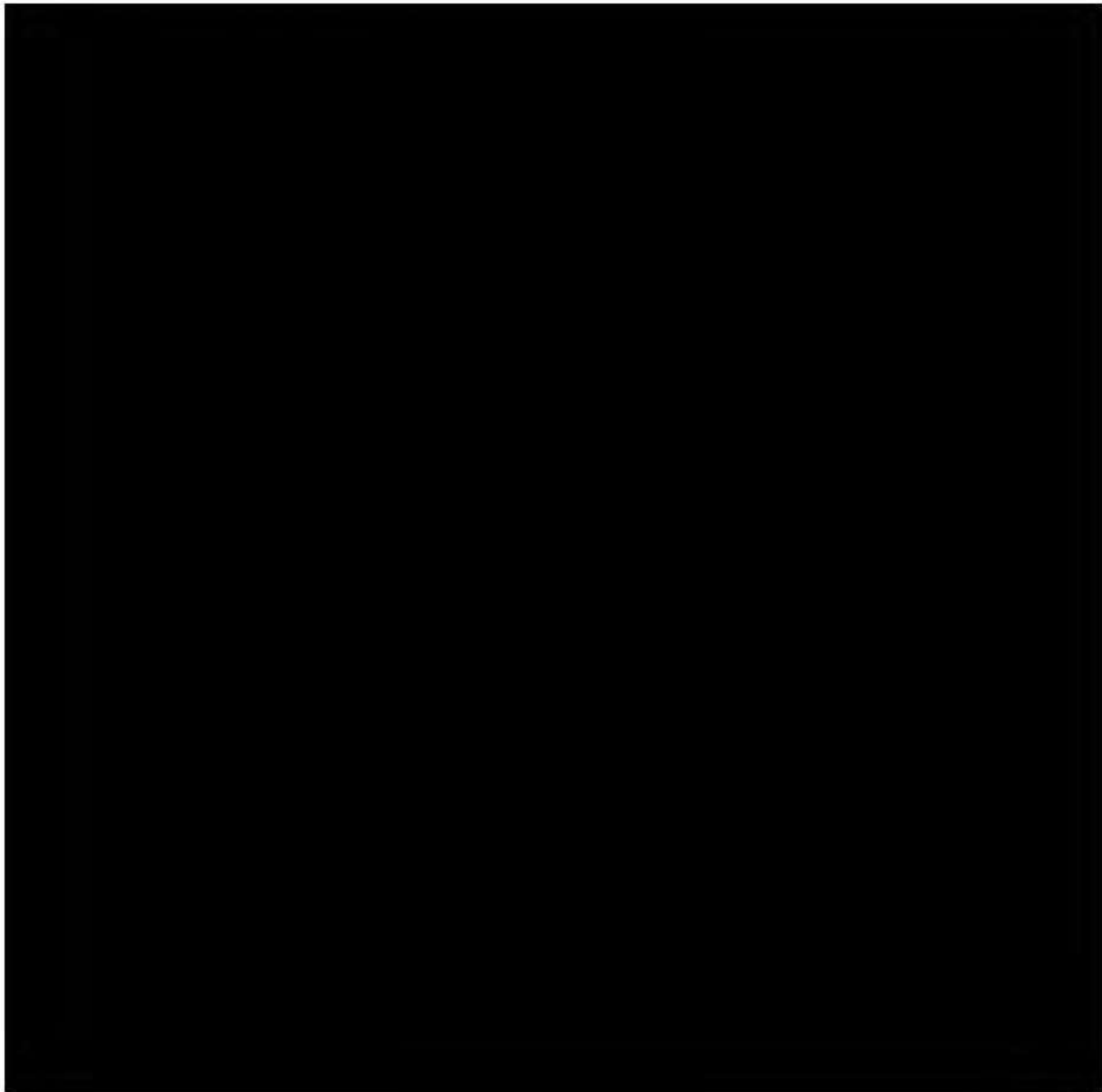
d) Dr. Scott Morton's Analysis of Illumina's Pre- and Post-Merger Profits Demonstrates Quantitatively Illumina's Incentive to Foreclose and Raise Costs to GRAIL's Rivals

3174. [REDACTED] } (PX6090 (Scott Morton Report) ¶¶ 194-97 (*in camera*)).

3175. Dr. Scott Morton's analysis of Illumina's incentives employed [REDACTED]  
[REDACTED] } (PX6090 (Scott Morton Report) ¶¶ 194-97, Table 2, n. 1-6 (*in camera*)).

3176. Table 2 below reflects the results of Dr. Scott Morton's analysis of Illumina's incentives before and after acquiring Grail:

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}

(PX6090 (Scott Morton Report) ¶ 194 *(in camera)*).

3177.

[REDACTED] } (PX6090 (Scott Morton Report) ¶¶ 194-97 *(in camera)*). }  
[REDACTED] } (PX6090 (Scott Morton Report) ¶¶ 194-97 *(in camera)*). }  
[REDACTED] (PX6090 (Scott Morton Report) ¶¶ 194-97 *(in camera)*).

3178.

[REDACTED] } (PX6090 (Scott Morton Report) ¶¶ 194, 196 *(in camera)*). }  
[REDACTED] (PX6090 (Scott Morton Report) ¶¶ 194, 196 *(in camera)*). }  
[REDACTED] (PX6090 (Scott Morton Report) ¶¶ 194, 197 *(in camera)*).

3179.

[REDACTED] } (PX6090 (Scott Morton Report) ¶¶ 194-97 *(in camera)*).

3180.

[REDACTED] } (PX6090 (Scott Morton Report) ¶¶ 194-97 *(in camera)*).

3181.

[REDACTED] } (PX6090 (Scott Morton Report) ¶¶ 194-97 *(in camera)*).

3182. Based on her comparisons of Illumina’s pre-merger and post-merger gross profit calculations, Dr. Scott Morton concluded,

[REDACTED]

(PX6090 (Scott Morton Report) ¶ 194 *(in camera)*).

3183. [REDACTED] (PX7138 (Scott Morton Trial Dep. at 31-32) *in camera*)).

3184. [REDACTED] } (PX7138 (Scott Morton Trial Dep. at 85) *in camera*)).

3185. [REDACTED] } (PX7138 (Scott Morton Trial Dep. at 57) *in camera*)).

3186. [REDACTED] (PX7138 (Scott Morton Trial Dep. at 65-66) *in camera*)).

3187. [REDACTED] (PX7138 (Scott Morton Trial Dep. at 66-67) *in camera*)).

3188. [REDACTED] } (PX6090 (Scott Morton Report) ¶¶ 199-203 *in camera*)).

**3. Other MCED Tests Are Likely to Compete Closely with Galleri**

a) Other MCED Developers Are Targeting the Same MCED Space

3189. [REDACTED]

3190. [REDACTED] } (*See e.g.*, Ofinan (Grail) Tr. 3303-05; Nolan (Freenome) Tr. 2756-59 *in camera*); Getty (Guardant) Tr. 2537-39; Conroy (Exact) Tr. 1615 *in camera*); PX7121 (Otte (Freenome) Dep. at 29-31) *in camera*)).

3191. [REDACTED] } (PX7087 (Goswami (Illumina) Dep. at 1223 (*in camera*)))

3192. [REDACTED] } (Strom (Morgan Stanley) Tr. 3556-58 (*in camera*) (discussing PX8458 (Morgan Stanley) at 001, 003 [REDACTED] } (*in camera*)).

3193. Respondents’ expert, Dr. Katz agreed that “MCED test developers are undertaking development efforts in the hope that they will succeed in the marketplace for multicancer early detection tests[.]” (RX6004 (Katz Trial Dep. at 99)).

3194. Respondents’ expert, Dr. Katz, testified that racing to be the first to launch a product to market is a dimension of competition. (RX6004 (Katz Trial Dep. at 100)).

3195. Respondents’ expert, Dr. Katz, testified that firms competing as part of R&D competition may assess their competitors’ products. (RX6004 (Katz Trial Dep. at 102)).

3196. Respondents’ expert, Dr. Katz, testified that monitoring rivals can drive competition. (RX6004 (Katz Trial Dep. at 103)).

3197. Respondents’ expert, Dr. Katz, testified that monitoring rivals can also be an “input[] into the decision-making process of how much to invest or in what ways to invest[.]” (RX6004 (Katz Trial Dep. at 103)).

3198. Respondents’ expert, Dr. Katz, testified that firms that are developing MCED tests have identified other MCED developers as competitors. (RX6004 (Katz Trial Dep. at 104)).

3199. Respondents’ expert, Dr. Katz, testified that firms developing MCED tests have assessed their rivals’ product features for their MCED tests. (RX6004 (Katz Trial Dep. at 104)).

3200. Mr. Bishop testified that he was aware that companies including Exact, Thrive, Guardant, Singlera, and Burning Rock had indicated an intent to develop a multicancer test. (PX7069 (Bishop (Grail) IHT at 127-28)).

3201. Mr. Bishop identified “many and varied” types of information for learning about these cancer screening companies, including “press reports, different presentations from companies in the field, medical conferences and symposia, [and] journal publications.” (PX7069 (Bishop (Grail) IHT at 125-127)).

3202. In an email discussing Grail’s investor relations, dated July 7, 2020, Grail CEO Hans Bishop stated that [REDACTED]

[REDACTED] } (PX4241 (Grail) at 002 (Email from H. Bishop, Grail, to A. Jasmshidi, Grail, et al., July 7, 2020) (*in camera*)).

3203. In the same July 7, 2020 email, Mr. Bishop noted that [REDACTED] } (PX4241 (Grail) at 002 (Email from H. Bishop, Grail, to A. Jasmshidi, Grail, et al., July 7, 2020) (*in camera*)).

(1) Exact and Thrive

(a) *Exact/Thrive is Developing an MCED Test*

3204. [REDACTED] } (PX7091 (Lengauer (Third Rock Ventures) Dep. at 13-14) (*in camera*)).

3205. [REDACTED] } (Conroy (Exact) Tr. 1650 (*in camera*)).

3206. [REDACTED] } (Conroy (Exact) Tr. 1650 (*in camera*)).

3207. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 194 (*in camera*)).

3208. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 194 (*in camera*)).

3209. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 53-55, 57-58) (*in camera*)).

3210. [REDACTED] } (Conroy (Exact) Tr. 1571 (*in camera*)).

(b) [REDACTED]

3211. [REDACTED] } (PX8530 (Exact/Thrive) at 003 (Thrive, All Hands Meeting Talk Track, Sept. 21, 2020)); *see also* (PX7085 (Harada (Exact) Dep. at 227) (*in camera*)).

3212. [REDACTED] } (Conroy (Exact) Tr. 1614 (*in camera*)).

- 3213. [REDACTED] (PX7051 (Lengauer IHT at 176-77) (*in camera*)).
- 3214. [REDACTED] (Conroy (Exact) Tr. 1614 (*in camera*)).
- 3215. [REDACTED] } (Conroy (Exact) Tr. 1662 (*in camera*)).
- 3216. [REDACTED] } (Conroy (Exact) Tr. 1614 (*in camera*)).
- 3217. [REDACTED] (Conroy (Exact) Tr. 1614 (*in camera*)).
- 3218. [REDACTED] }. (Conroy (Exact) Tr. 1614-15 (*in camera*)).
- 3219. [REDACTED] } (Conroy (Exact) Tr. 1558-59 (*in camera*)); PX7058 (Conroy (Exact) IHT at 143 (*in camera*)) ( [REDACTED] })).
- 3220. [REDACTED] } (Lengauer (Third Rock Ventures) Tr. 196 (*in camera*); see also Conroy (Exact) Tr. 1617-18 (*in camera*)) [REDACTED] }.
- 3221. [REDACTED] (Conroy (Exact) Tr. 1615 (*in camera*)).
- 3222. [REDACTED] (Conroy (Exact) Tr. 1615 (*in camera*)).
- 3223. [REDACTED] } (Conroy (Exact) Tr. 1616-17 (*in camera*)).



3224. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 58 (*in camera*))); PX7051 (Lengauer (Third Rock Ventures) IHT at 142-43 (*in camera*)).

3225. [REDACTED] } (PX7110 (Conroy (Exact) Dep. at 247-48) (*in camera*); see also PX7058 (Conroy (Exact) IHT at 111-13 (*in camera*)).

3226. [REDACTED] } (PX7085 (Harada (Exact) Dep. at 229-30 (*in camera*)).

3227. [REDACTED] (PX7085 (Harada (Exact) Dep. at 233 (*in camera*)).

3228. [REDACTED] } (Conroy (Exact) Tr. 1617 (*in camera*)).

3229. [REDACTED] } (PX7058 (Conroy (Exact) IHT at 114-15) (*in camera*)).

3230. [REDACTED] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 142-43 (*in camera*)).

(c) *Grail Considers Exact/Thrive a Competitor*

3231. A May 2021 Grail AACR Conference Report identifies Exact/Thrive as Grail’s “most significant competitor in [the] MCED space.” (PX4616 (Grail) at 030 (AACR Conference Report, May 5, 2021)).

3232. [REDACTED] (PX4048 (Grail) at 002, 004 (*in camera*)).

3233. [REDACTED] (PX4075 (Grail) at 009, 027 (Email from A. Aravanis, Grail, to M.

Young, Grail, attaching, “Competitive Intelligence: An Overview,” Aug. 14, 2019) (*in camera*)).

3234. [REDACTED] (PX4075 (Grail) at 032 (Email from A. Aravanis, Grail, to M. Young, Grail, attaching, “Competitive Intelligence: An Overview,” Aug. 14, 2019 (*in camera*))).

3235. [REDACTED] (PX4288 (Grail) at 001 (Email exchange between H. Bishop, Grail, and R. Currie et al., Grail, July 8, 2020 (*in camera*))).

3236. [REDACTED] (PX4048 (Grail) at 007 [REDACTED] (*in camera*) (further noting that [REDACTED] )).

3237. [REDACTED] (PX4048 (Grail) at 006 [REDACTED] (*in camera*)).

3238. [REDACTED] (PX4207 (Grail) at 052 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (*in camera*)).

3239. [REDACTED] (Della Porta (Grail) Tr. 482-83 (*in camera*); PX4145 (Grail) at 009 (Competitive Intelligence, Aug. 14, 2019 (*in camera*))).

3240. [REDACTED] (PX4142 (Grail) at 067 [REDACTED] (*in camera*))).

3241. Grail described Exact and Thrive as “competitors” in its SEC S-1 filing. (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

3242. [REDACTED] (PX6049 (Grail) at 035 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

3243. [REDACTED] } (PX4145 (Grail) at 021 (*in camera*)).

3244. [REDACTED] } (PX4145 (Grail) at 033 (Competitive Intelligence, Aug. 14, 2019) (*in camera*); see also Della Porta (Grail) Tr. 492-93 (*in camera*)).

3245. Hans Bishop, Grail's CEO, asked [REDACTED] } (PX4443 (Grail) at 002-03 (Email from J. Ofman, Grail, to A. Chen et al., Grail, June 13, 2020) (*in camera*)). Josh Ofman, its Chief Medical Officer and External Affairs, described [REDACTED] } (PX4443 (Grail) at 002-03 (Email from J. Ofman, Grail, to A. Chen et al., Grail, June 14, 2020) (*in camera*)).

3246. [REDACTED] (PX4443 (Grail) at 002 (Email from J. Ofman, Grail, to A. Chen et al., Grail, June 14, 2020) (*in camera*)).

3247. [REDACTED] } (PX4023 (Grail) at 001 (Email from A. Chen, Grail, to J. Ofman et al., Grail, Jun. 15, 2020 (*in camera*))).

3248. In July 2020, Grail's CEO [REDACTED] (PX4007 (Grail) at 002 (Email from A. Chen, Grail, to Grail's Executive Leadership Team, et al., July 15, 2020) (*in camera*) (further stating that [REDACTED] })).

3249. In an internal email discussing [REDACTED]

[REDACTED] } (PX4318 (Grail) at 001 (Email from R. Currie, Grail, to J. Ofman, et al., Grail, July 30, 2020) (*in camera*)).

(d) [REDACTED]

3250. [REDACTED] } (Bishop (Grail) Tr. 1487 (*in camera*); PX4442 (Grail) at 001-02 [REDACTED] (*in camera*)).

3251. [REDACTED] (PX4443 (Grail) at 003 (Email from A. Chen, Grail, to J. Ofman, Grail, Jun. 13, 2020 (*in camera*))).

3252. [REDACTED] } (PX4456 (Grail) at 002 [REDACTED] (*in camera*); *see also* (Bishop (Grail) Tr. 1491 (*in camera*))).

3253. [REDACTED] } (PX4006 (Grail) at 001 (Email from A. Chen, Grail, to Executive Leadership Team et al., Grail, July 7, 2020) (*in camera*)).

3254. [REDACTED] (Bishop (Grail) Tr. 1486-88 (*in camera*); PX4442 (Grail) at 001-02 [REDACTED] (*in camera*)).

3255. [REDACTED] (Bishop (Grail) Tr. 1485-86, 1497 (*in camera*)).

3256. [REDACTED] (PX4441 (Grail) at 002, 004 [REDACTED] (*in camera*)).

3257. [REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

(PX4456 (Grail) at 002 [REDACTED]  
[REDACTED] (in camera)).

3258. [REDACTED]

(PX4456 (Grail) at 002 [REDACTED] (in camera)).

3259. [REDACTED]

(PX4456 (Grail) at 012 [REDACTED] (in camera)).

3260. In an internal presentation labeled [REDACTED]

[REDACTED]

(PX4554 (Grail) at 003-04 [REDACTED] (in camera)).

3261. In an internal presentation labeled [REDACTED]

[REDACTED] (PX4554 (Grail) at 008 [REDACTED] (in camera)).

(PX4554 (Grail) at 008 [REDACTED] (in camera)).

3262.

[REDACTED]

{

[REDACTED]

}

(PX4456 (Grail) at 012-13

[REDACTED]

(*in camera*)).

3263.

[REDACTED] (PX4441 (Grail) (*in camera*)).

[REDACTED] }  
(PX4441 (Grail) at 003 [REDACTED]  
(in camera)).

(i) [REDACTED] }

3264. [REDACTED]  
(PX4456 (Grail) at 013  
(in camera)). [REDACTED]  
[REDACTED] } (PX4456 (Grail) at 013  
(in camera)).

(ii) [REDACTED]

3265. [REDACTED]  
(PX4456 (Grail) at 005 [REDACTED]  
(in camera)).

3266. In an email sent on July 5, 2020, Hans Bishop, Grail’s CEO, remarked that [REDACTED]  
[REDACTED] } (PX4241 (Grail) at 005 (Email from H. Bishop, Grail, to A. Freidin, Grail, July  
5, 2020) (in camera)).

3267. Dr. Ofman explained that, in an interventional study, patients’ test results are returned to  
the health care provider, who then apply those results to aid their patients. (PX7092  
(Ofman (Grail) Dep. at 253)).

3268. In an email discussing a “Round Table” meeting sent to Grail’s Executive Team on May  
5, 2020, Nichole D’Arco, Grail’s Associate Director of Internal Communications,  
identified a list of questions to discuss at the meeting—including “[h]ow does Thrive’s  
DETECT-A compare to our test? Are there any competitive advantages?” and “how [does]  
their DETECT-A study design compare[ ] to PATHFINDER.” (PX4315 (Grail) at 001  
(Email from N. D’Arco, Grail, to Grail’s Executive Team et al., Grail, May 5, 2020)).

3269. [REDACTED]  
[REDACTED] } (PX4207 (Grail) at  
033 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (in camera)).  
[REDACTED]  
[REDACTED] } (PX4207 (Grail) at 033 (Competitive Intelligence Updates: Deep Dive, June  
9, 2020) (in camera)).

3270.

[REDACTED] } (PX4456 (Grail) at 012 (in camera)). [REDACTED] (PX4456 (Grail) at 012 (in camera)).

3271.

[REDACTED] } (PX4456 (Grail) at 012 (in camera)). [REDACTED] } (PX4456 (Grail) at 012 (in camera)).

3272. In July 2020, Josh Ofman, Chief Medical Officer, and Alice Chen, Grail VP of Product and Head of Program Management Organization, emailed with other Grail executives regarding [REDACTED]

[REDACTED] (PX4027 (Grail) at 001-004 (Email from J. Ofman, Grail, to A. Chen, et al., Grail, July 29, 2020) (in camera)).

3273.

[REDACTED] } (PX4456 (Grail) at 012 (in camera)). [REDACTED] } (PX4456 (Grail) at 012 (in camera)).

(iii) [REDACTED]

3274.

[REDACTED] } (PX4456 (Grail) at 013 (in camera)). [REDACTED]



[REDACTED]

(PX4456 (Grail) at 013 [REDACTED] (in camera)).

3275. Hans Bishop, Grail’s CEO, emailed Alice Chen and other Grail executives on July 8, 2020, with [REDACTED] Bishop wrote: [REDACTED] (PX4442 (Grail) at 001 [REDACTED] (in camera)).

3276. In an email dated July 15, 2020, Josh Ofman, Grail’s Chief Medical Officer and External Affairs, wrote [REDACTED] (PX4007 (Grail) at 001 (Email from J. Ofman, Grail, to A. Chen, Grail, et al., July 15, 2020) (in camera)). Dr. Ofman also asked [REDACTED] (PX4007 (Grail) at 001 (Email from J. Ofman, Grail, to A. Chen, Grail, et al., July 15, 2020) (in camera)).

3277. [REDACTED] (Della Porta (Grail) Tr. 487 (in camera)); PX4145 (Grail) at 024 (Grail, “Competitive Intelligence,” Aug. 14, 2019) (in camera)). [REDACTED] (Della Porta (Grail) Tr. 487 (in camera)). [REDACTED] (Della Porta (Grail) Tr. 487 (in camera)).

[REDACTED] }  
(Della Porta (Grail) Tr. 488 (*in camera*)).

(iv) [REDACTED] }

3278. On May 3, 2020, Alex Aravanis, Grail’s Chief Scientific Officer and Head of R&D, circulated [REDACTED] } (PX4074 (Grail) at 001 (Email from A. Aravanis, Grail, to Grail’s Executive Leadership Team, et al., May 3, 2020) (*in camera*)). Dr. Aravanis highlighted [REDACTED] } (PX4074 (Grail) at 001 (Email from A. Aravanis, Grail, to Grail’s Executive Leadership Team, et al., May 3, 2020) (*in camera*)). [REDACTED] } (PX4074 (Grail) at 099 (Grail, “Science, Medicine, and Technology Board Subcommittee Meeting,” May 2, 2020) (*in camera*)).

3279. [REDACTED] } (PX4198 (Grail) at 005 [REDACTED] } (*in camera*)).

3280. Hans Bishop, Grail’s CEO, emailed Alice Chen and other Grail executives on July 8, 2020, with [REDACTED] } Bishop wrote: [REDACTED] } (PX4442 (Grail) at 001 [REDACTED] } (*in camera*)).

3281. [REDACTED] } (PX4456 (Grail) at 005 [REDACTED] } (*in camera*)). [REDACTED] } (PX4456 (Grail) at 005 [REDACTED] } (*in camera*)).

3282. [REDACTED] } (PX4456 (Grail) at 005 [REDACTED] } (*in camera*)).

3283.

[REDACTED] (PX4456 (Grail) at 012 (in camera)). [REDACTED]

[REDACTED]

(PX4456 (Grail) at 012 [REDACTED] (in camera)).

3284.

[REDACTED] (PX4456 (Grail) at 013 (in camera)). [REDACTED] (PX4456 (Grail) at 013 (in camera)). [REDACTED] (PX4456 (Grail) at 013 (in camera)).

(2) Guardant

(a) *Guardant Is Developing an MCED Test*

3285. Guardant is currently developing an MCED test and plans to initiate MCED test trials in the near future. (Getty (Guardant) Tr. 2497).

3286. In an email dated September 10, 2020, Mark Morgan, Grail’s SVP of Market Access & Health System Partnerships, wrote to Scott Osler, Grail’s Senior Director of Employer Partnerships, stating that “Guardant is [ ] working on a pan cancer assay (Lunar) but instead of going for all cancers, they are starting with colorectal given there is a reimbursement pathway (similar to [C]ologuard).” (PX4194 (Grail) at 001 (Email from M. Morgan, Grail, to S. Osler, Grail, Sept. 10, 2020)).

3287.

[REDACTED] } (Getty (Guardant) Tr. 2533, 2537 (in camera)).

3288.

[REDACTED] } (Getty (Guardant) Tr. 2537-38 (in camera)).

(b) *Guardant Considers Grail a Competitor*

3289. Guardant views Grail, Natera, Exact, and Freenome as competitors in MCED test development. (Getty (Guardant) Tr. 2687-88).
3290. Guardant anticipates that its LUNAR-2 test will compete with Galleri; Guardant is “really focused” on Grail as a competitor. (Getty (Guardant) Tr. 2505-07).
3291. [REDACTED] (Getty (Guardant) Tr. 2566 *(in camera)*).  
[REDACTED] } (Getty (Guardant) Tr. 2566 *(in camera)*).
3292. [REDACTED] } (PX7105 (Getty (Guardant) Dep. at 37) *(in camera)*; see also PX7040 (Getty (Guardant) IHT at 157) (describing Grail as “a competitor and a formidable one at that.”)).
3293. [REDACTED] } (PX8503 (Guardant) at 066 *(in camera)*).

(c) *Grail Considers Guardant a Competitor*

3294. [REDACTED] (Della Porta (Grail) Tr. 484-85 *(in camera)*); PX4145 (Grail) at 017 (Grail, “Competitive Intelligence,” Aug. 14, 2019) *(in camera)*).
3295. [REDACTED] } (PX4018 (Grail) at 005 *(in camera)*).
3296. [REDACTED] (PX4018 (Grail) at 006 *(in camera)*); PX4052 (Grail) at 044 (Grail, “Grail Strategy Workshop #1,” Aug. 17, 2020) *(in camera)*).
3297. [REDACTED] (Della Porta (Grail) Tr. 482 *(in camera)*); PX4145 (Grail) at 009 (Grail, “Competitive Intelligence,” Aug. 14, 2019) *(in camera)*).
3298. Grail described Guardant as a “competitor” in its SEC S-1 filing. (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

3299. An internal Grail Excel spreadsheet, which [REDACTED] [REDACTED] } (PX4011 (Grail) at 003-005 [REDACTED] (in camera)).

3300. In an internal presentation labeled [REDACTED] [REDACTED] (PX4267 (Grail) at 032 [REDACTED] (in camera)). Grail further mentioned [REDACTED] [REDACTED] } (PX4267 (Grail) at 036 [REDACTED] (in camera)).

3301. [REDACTED] [REDACTED] } (Della Porta (Grail) Tr. 486 (in camera)); PX4145 (Grail) at 017 (Grail, "Competitive Intelligence," Aug. 14, 2019) (in camera)). [REDACTED] [REDACTED] } (Della Porta (Grail) Tr. 486 (in camera)). [REDACTED] } (Della Porta (Grail) Tr. 486 (in camera)).

3302. [REDACTED] [REDACTED] } (PX4075 (Grail) at 010, 017 (Grail, Competitive Intelligence: An Overview, Aug. 14, 2019) (in camera)).

3303. [REDACTED] [REDACTED] } (PX4075 (Grail) at 017 (Grail, Competitive Intelligence: An Overview, Aug. 14, 2019) (in camera)).

3304. [REDACTED] [REDACTED] (PX4075 (Grail) at 017 (Grail, Competitive Intelligence: An Overview, Aug. 14, 2019) (in camera)).

3305. [REDACTED] [REDACTED] (Della Porta (Grail) Tr. 506 (in camera); PX4266 (Grail) at 045-046 [REDACTED] (in camera)).

3306. In an internal memo dated September 28, 2020, Grail noted that [REDACTED] [REDACTED]



3314. Mr. Nolan testified that Freenome considers Grail to be an MCED competitor. (Nolan (Freenome) Tr. 2727; *see also* Nolan (Freenome) Tr. 2777 (*in camera*) ( [REDACTED] }; PX7094 (Nolan (Freenome) Dep. at 260-62) (*in camera*) ( [REDACTED] })).

3315. [REDACTED] (Nolan (Freenome) Tr. 2774 (*in camera*)).

3316. [REDACTED] (Nolan (Freenome) Tr. 2774-75 (*in camera*)).

3317. [REDACTED] (PX7094 (Nolan (Freenome) Dep. at 262-63) (*in camera*)).

3318. [REDACTED] (PX8368 (Freenome) at 079 (Crossover Round Company Overview, 2020) (*in camera*) ( [REDACTED] }; PX7055 (Otte (Freenome) IHT at 83) (*in camera*) ( [REDACTED] })); *see* PX7050 (Nolan (Freenome) IHT at 85) (*in camera*); *see also* PX7121 (Otte (Freenome) Dep. at 148 (*in camera*)).

(c) *Grail Considers Freenome a Competitor*

3319. [REDACTED] (PX4075 (Grail) at 009, 033-37 (Email from A. Aravanis, Grail to M. Young and H. Bishop, Grail, attaching Competitive Intelligence: An Overview, Sept. 7, 2019) (*in camera*)).

3320. [REDACTED] (PX4018 (Grail) at 005 [REDACTED] (*in camera*)).

3321. [REDACTED] (PX4018 (Grail) at 006 [REDACTED] )

[REDACTED] (*in camera*); PX4052 (Grail) at 044 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

3322. [REDACTED] } (Della Porta (Grail) Tr. 483 (*in camera*)); PX4145 (Grail) at 009 (Competitive Intelligence: An Overview, Aug. 14, 2019 (*in camera*)).

3323. [REDACTED] } (PX4444 (Grail) at 013  
[REDACTED] (*in camera*); see also PX4054 (Grail) at 012 [REDACTED] (*in camera*)).

3324. [REDACTED] } (PX6049 (Grail) at 035 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

3325. [REDACTED] } (PX6049 (Grail) at 036 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

(4) Singlera

(a) *Singlera Is Developing an MCED Test*

3326. Singlera is currently developing an MCED test referred to as the PanSeer test. (PX7102 (Gao (Singlera) Dep. at 23-24)).

3327. Singlera conducted a clinical study of PanSeer, called the Taizhou Longitudinal Study. (Gao (Singlera) Tr. 2877-78). The Taizhou Longitudinal Study involved the collection of blood plasma samples from over 120,000 healthy (asymptomatic) subjects who were subsequently monitored for cancer occurrence. (RX1699 (Illumina) (Email from M. Nguyen, Illumina, to J. Godsey et al., Illumina attaching Chen X. et al., Non-invasive Early Detection of Cancer Four Years before Conventional Diagnosis Using a Blood Test,” *Nature Communications* 11:3475 (2020), July 21, 2020)).

3328. Singlera published a paper in *Nature* in 2020 based on data from the Taizhou Longitudinal Study, which reported on Panseer’s sensitivity and specificity at detecting five different cancers. (Gao (Singlera) Tr. 2879-80; RX1699 (Illumina) (Email from M. Nguyen, Illumina, to J. Godsey et al., Illumina attaching Chen X. et al., Non-invasive Early Detection of Cancer Four Years before Conventional Diagnosis Using a Blood Test,” *Nature Communications* 11:3475 (2020), July 21, 2020)).