3329. Singlera plans to demonstrate the PanSeer test's ability to detect more cancers than the five demonstrated in the TLS study. (Gao (Singlera) Tr. 2881-82 (further explaining that the PanSeer test is designed to detect "all kinds of cancer," and not just the five cancers used in the TLS study)).

3330. Dr. Gao testified that Singlera's "goal is pan-cancer" for the PanSeer test. (Gao (Singlera) Tr. 2881).

(b) Singlera Considers Grail a Competitor

3331. Singlera views Grail's Galleri test as a competitor to PanSeer. (PX7042 (Gao (Singlera) IHT at 96-97)).

3332. Dr. Gao testified that Singlera is "ahead of [Grail]" based on its publication of results from Singlera's Taizhou Longitudinal Study. (Gao (Singlera) Tr. 2950).

3333. Singlera expects its PanSeer test to compete directly with Grail's Galleri test once on the market. (PX7042 (Gao (Singlera) IHT at 98-99)).

3334. Singlera expects to compete with Grail on price, efficacy, and innovation of its MCED test. (PX7042 (Gao (Singlera) IHT at 98-100)). Further, Gary Gao, Singlera's Co-Founder and current Scientific Advisor, testified that he expects that the company's MCED test will compete on "accuracy, sensitivity, [and] specificity" of the tests. (PX7042 (Gao (Singlera) IHT at 99-100)).

(c) Grail Considers Singlera a Competitor

3335. {[redacted]} (PX4075 (Grail) at 009, 038-43 (Email from A. Aravanis, Grail to M. Young and H. Bishop, Grail, attaching Competitive Intelligence: An Overview, Sept. 7, 2019) (*in camera*)).

3336. {[redacted]} (PX4018 (Grail) at 005 [redacted] (*in camera*)).

3337. {[redacted]} (PX4018 (Grail) at 006 [redacted] (*in camera*); PX4052 (Grail) at 044 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

3338. {[redacted]} (Della Porta (Grail) Tr. 483 (*in camera*)); PX4145 (Grail) at 009 (Grail, Competitive Intelligence: An Overview, Aug. 14, 2019 (*in camera*)).

3339. Grail described Singlera as a "competitor" in its SEC S-1 filing. (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

3340. In a November 2018 Grail Board Meeting, Mr. Alex Aravanis, Grail's then head of research and development, discussed Singlera being "a competitor who is developing something overlapping with GRAIL" because of Singlera's "interesting methylation technology." (PX4340 (Grail) at 004 (Email from F. Yu, Ally Bridge, to A. Aravanis, Grail, Nov. 12, 2018)).

3341. {[redacted]} (PX4267 (Grail) at 048 [redacted] (*in camera*)).

3342. {[redacted]} (PX4145 (Grail) at 044 (Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*)).

3343. {[redacted]} (PX4145 (Grail) at 044 (Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*); *see also* Della Porta (Grail) Tr. 495 (*in camera*) ({[redacted]})).

3344. {[redacted]} (PX4025 (Grail) at 001 (Email from M. Sturm, Grail, to R. Licata et al., Grail, Sept. 3, 2020) (*in camera*)).

3345. {[redacted]} (Della Porta (Grail) Tr. 495 (*in camera*)). {[redacted]} (Della Porta (Grail) Tr. 495-96 (*in camera*)). {[redacted]} (Della Porta (Grail) Tr. 496 (*in camera*)).

3346. {[redacted]} (PX4048 (Grail) at 015 [redacted] (*in camera*)).

3347. {[redacted]}. (PX4011 (Grail) [redacted] (*in camera*)).

3348. {[redacted]} (Della Porta (Grail) Tr. 496-97 (*in camera*)).

3349. {[redacted]} (PX4049 (Grail) at 002 (Email from A. Chen, Grail, to M. Young et al., Grail, Jul. 27, 2020) (*in camera*)).

3350. {[redacted]} (PX6049 (Grail) at 037 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

(5) [redacted]

3351. [redacted]

3352. [redacted]

3353. [redacted]

3354. [redacted]

3355. [redacted]

3356. [redacted]

3357. [redacted]

3358. [redacted]

3359. [redacted]

3360. [redacted]

3361. [redacted]

(6) Helio (LAM)

(a) Helio Is Developing an MCED Test

3362. Helio is developing an early detection test for liver cancer and colon cancer. (Chahine (Helio) Tr. 1000, 1033).

3363. Dr. Kenneth Chahine, Board Advisor to Helio and former CEO of Helio, testified that Helio's test will eventually evolve into a MCED test: "[W]here GRAIL has chosen to do multiple cancers at one time, Helio and a few others have taken a strategic approach to say let's get one cancer done right and then add a second and a third and a fourth." (Chahine (Helio) Tr. 1031-32) (further explaining that "it would be hard to find anyone in this industry that would say that all of these tests aren't eventually going to become a multicancer screening test").

(b) [redacted]

3364. Dr. Chahine testified: {[redacted]} (PX7077 (Chahine (Helio) Dep. at 83) (*in camera*)).

3365. {[redacted]} (RX0894 (Helio) at 24 (Helio Health, May 31, 2021) (*in camera*); *see also id.* at 19 {[redacted]}.

3366. {[redacted]} (PX8655 (Helio) at 031 (*in camera*) ({[redacted]}).

3367. {[redacted]} (Chahine (Helio) Tr. 1067 (*in camera*); *see also* PX7077 (Chahine (Helio) Dep. at 64, 82-83 (*in camera*)); PX8652 (Helio) at 001 [redacted] (*in camera*)).

3368. {[redacted]} (PX7077 (Chahine (Helio) Dep. at 82-84) (*in camera*)).

3369. {[redacted]} (Chahine (Helio) Tr. 1112-13 (*in camera*)).

(c) Grail Considers Helio a Competitor

3370. {[redacted]} (PX4075 (Grail) at 009, 038-43 (Email from A. Aravanis, Grail, to M. Young attaching Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*)).

3371. {[redacted]} (Della Porta (Grail) Tr. 483 (*in camera*)); PX4145 (Grail) at 009 (Grail, "Competitive Intelligence," Aug. 14, 2019 (*in camera*)). {[redacted]} (Della Porta (Grail) Tr. 483 (*in camera*)). {[redacted]} (Della Porta (Grail) Tr. 483 (*in camera*)).

3372. Grail described "Laboratory for Advanced Medicine" (Helio) as a "competitor" in its SEC S-1 filing. (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020).

3373. {[redacted]} (PX4018 (Grail) at 007 [redacted] (*in camera*)).

3374. {[redacted]} (PX4250 (Grail) at 011 (Grail, {[redacted]} (*in camera*)).

3375. Grail identified Helio as a company it had been tracking in its "CIA Monthly Newsletter" for December 2020. (PX4129 (Grail) at 001 (Grail, "Grail CIA Monthly Newsletter: December 2020")). Its newsletter noted that Helio "over the last few months has been building a strong leadership team (Ancestry, Amazon)." (PX4129 (Grail) at 001 (Grail, "Grail CIA Monthly Newsletter: December 2020")).

(7) {[redacted]}

(a) {[redacted]}

3376. [redacted]

(b) {[redacted]}

3377. {[redacted]}

3378. {[redacted]}

3379. {[redacted]}

3380. {[redacted]}

(c) {[redacted]}

3381. As of August 17, 2020, Grail identified {[redacted]} (PX4052 (Grail) at 045 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

3382. {[redacted]} (PX4018 (Grail) at 007 [redacted]

3383. In an internal memo discussing {[redacted]} (PX4053 (Grail) at 005 (Highlights from the Cowen 2020 Liquid Biopsy Summit by Cowen) (*in camera*)). {[redacted]} (PX4053 (Grail) at 005 (Highlights from the 2020 Liquid Biopsy Summit by Cowen) (*in camera*)).

3384. {[redacted]} (PX6049 (Grail) at 040 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

(8) Grail Tracked Other Companies as Competitors in the Cancer Screening Space

3385. Grail identified Burning Rock as a competitor in the early cancer detection space in its IPO prospectus. (PX4082 (Grail) at 036, 127 (Email attaching Grail S-1/Amended, Sept. 2020)).

3386. Mr. Bishop, Grail's previous CEO, testified that Burning Rock is currently developing a cancer screening test and has declared its intent to develop a multicancer test. (PX7069 (Bishop (Grail) IHT at 124-27)).

3387. As of December 2020, Grail CIA Monthly Newsletter identifies Delfi as a competitor. (PX4129 (Grail) at 001 (Grail CIA Monthly Newsletter, Dec. 2020)).

3388. {[redacted]} (PX6049 (Grail) at 037, [redacted]

b) {[redacted]}

3389. {[redacted]} (*See, e.g.*, (PX4066 (Grail) at 003 (Email from Hans Bishop, Grail, to C. Della Porta, Grail, et al., July 14, 2019); PX4005 (Grail) at 001 (Email from V. Demas, Grail, to Grail's Executive Leadership Team, et al.,

Sept. 28, 2020); PX4053 (Grail) at 001 (Highlights from the 2020 Liquid Biopsy Summit by Cowen) (*in camera*)); PX4021 (Grail) at 001 (Email from R. Currie, Grail, to H. Bishop, et al., Sept. 16, 2020); PX4519 (Grail) at 001 (Email from J. Owens, Grail, to C. Arnold, July 9, 2019); PX4046 (Grail) at 094 (Board of Directors Meeting, Feb. 14, 2019) (*in camera*); PX4111 (Grail) at 001 (Email from H. Bishop, Grail, to A. Freidin, Grail, et al., Oct. 27, 2020); PX4241 (Grail) at 002 (Email from H. Bishop, Grail, to A. Jamshidi, Grail, et al., July 7, 2020) (*in camera*).

3390. Grail's Form S-1, which was filed with the SEC in September 2020, states that the "testing and diagnostics products industry is intensely competitive." (PX4082 (Grail) at 036 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

3391. In August 2020, Grail identified { } (PX4052 (Grail) at 012 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

3392. In a document labeled { } (PX4150 (Grail) at 008 (Market Access & Evidence Subteam Charters) (*in camera*)).

3393. In a document labeled { } (PX4150 (Grail) at 032 (Market Access & Evidence Subteam Charters) (*in camera*)).

(1) Background on Grail Competitive Intelligence Team ("CIA Team")

3394. { } (PX7069 (Bishop (Grail) IHT at 35-36) (*in camera*)).

3395. Grail's CIA team was founded in 2018. (Della Porta (Grail) Tr. 465).

3396. Grail's CIA team doubled in size from 2018 to 2021. (Della Porta (Grail) Tr. 465-67).

3397. Grail's Senior Director of Growth Strategy, Mr. Della Porta, was the co-lead of Grail's CIA team until January 2021. (Della Porta (Grail) Tr. 465-67).

3398. In Mr. Della Porta's role as co-lead of the competitive intelligence team, he responded to specific requests for information from Grail leadership. (Della Porta (Grail) Tr. 466).

3399. { } (PX4075 (Grail) at 001

(Email from A. Aravanis, Grail, to M. Young, attaching Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*); *see* PX7083 (Bishop (Grail) Dep. at 48)).

3400. { [redacted] } (Bishop (Grail) Tr. 1473 (*in camera*); Della Porta (Grail) Tr. 465). The CIA Team's role is to monitor industry developments that were relevant to Grail. (Della Porta (Grail) Tr. 467). { [redacted] } (Bishop (Grail) Tr. 1473 (*in camera*); *see also* PX7083 (Bishop (Grail) Dep. at 55-56); PX7069 (Bishop (Grail) IHT at 35-36, 38) (*in camera*)).

3401. Grail's competitive intelligence team ("CIA Team") surveyed the scientific and commercial landscape in the context of cancer screening and related technologies. (Della Porta (Grail) Tr. 467-68).

3402. Grail's competitive intelligence team ("CIA Team") created competitive updates from conferences, profiles of technologies of interest, slide shows, and reports. (Della Porta (Grail) Tr. 468-69).

3403. Grail's Competitive Intelligence Team ("CIA team") would "meet every 4-6 weeks or at leadership's request to analyze significant events in [Grail's] space (e.g., conferences, earnings, publications)." (PX4263 (Grail) at 001 (Email from C. Della Porta, Grail, to C. Arnold, Grail, Apr. 12, 2019)).

(a) Grail's "CIA Team" Was Designed to Address a Number of Grail Commercial Objectives

3404. The { [redacted] } (PX4018 (Grail) at 002 (*in camera*); PX4444 (Grail) at 002 (*in camera*)).

3405. Chris Della Porta, Grail's Senior Director of Group Strategy, described the primary objective of Grail's CIA team as to "ensure GRAIL's commercial and product development strategies incorporate a rapidly evolving market landscape," which includes efforts to "ensure [Grail's] leadership is armed with knowledge of competitive strategies and tactics." (PX4263 (Grail) at 001 (Email from C. Della Porta, Grail, to C. Arnold, Grail, April 12, 2019)).

3406. In July 2020, Vicky Demas, Grail's Platform Product Manager and New Products Program Lead, wrote { [redacted]

- [redacted]

- [redacted]
- [redacted]

(PX4321 (Grail) at 001, Email from V. Demas, Grail, to Grail's Executive Leadership Team, July 16, 2020) (*in* camera); *see* PX4207 (Grail) at 005 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (*in camera*) ({[redacted]}).

3407. {[redacted]} (Della Porta (Grail) Tr. 497 (*in camera*)).

3408. {[redacted]} (Della Porta (Grail) Tr. 478-79 (*in camera*); PX4145 (Grail) at 006 (Competitive Intelligence, Aug. 14, 2019) (*in camera*) ({[redacted]}).

3409. {[redacted]} (Della Porta (Grail) Tr. 478 (*in camera*)). {[redacted]} (Della Porta (Grail) Tr. 478, 583 (*in camera*); *see also* Della Porta (Grail) Tr. 478, 583 (*in camera*) (stating that {[redacted]}).

3410. Grail's clinical development team analyzes the clinical trials of other companies that are developing MCED tests. (Della Porta (Grail) Tr. 582-83).

3411. {[redacted]} (Della Porta (Grail) Tr. 476 (*in camera*)). {[redacted]} Della Porta (Grail) Tr. 476 (*in camera*)). {[redacted]} (Della Porta (Grail) Tr. 476 (*in camera*)).

3412. [redacted] (Della Porta (Grail) Tr. 477, 480-81 (*in camera*) ([redacted]).

3413. [redacted] (PX4075 (Grail) at 008 (Email from A. Aravanis, Grail, to M. Young, attaching Competitive Intelligence: An Overview, Aug. 14, 2019) (*in camera*)). [redacted] (Bishop (Grail) Tr. 1477 (*in camera*)).

3414. Grail's CIA team began circulating a "Grail CIA Monthly Newsletter" that highlights news about relevant competitors in December 2020. (*See, e.g.*, PX4129 (Grail) (Grail CIA Monthly Newsletter, Dec. 2020); PX4059 (Grail) (Grail CIA Monthly Newsletter, Jan. 2021)). Grail circulated its "CIA Monthly Newsletter" to its Executive Leadership Team and others within the company. (*See, e.g.*, PX4131 (Grail) at 001-02 (Email from V. Demas, Grail, to Grail Executive Leadership Team, et al., Jan. 31, 2021)). To describe the newsletter, Grail's CIA team explained—"the team keeps top competitor summaries updated but also coordinates and consumes inputs from functional teams which we will be sharing in a monthly newsletter: Field Intelligence (work with sales – scope broader), Conference intelligence (MSL + Medical comms), MSL Intelligence (2nd degree information), Stakeholder events (what companies work with which KOLs), Investor conferences, Pub reviews (Medical comms), [and] Literature reviews and company assessments (R&D/New Products)." (PX4129 (Grail) at 001 (Grail CIA Monthly Newsletter, Dec. 2020)).

(b) "CIA Team" Work Product Is Used Widely Across a Variety of Grail Business Functions

3415. Chris Della Porta, Grail's Director of Growth Marketing, testified that accuracy was one of the competitive intelligence team's ("CIA Team") goals because of the various uses of the CIA Team's work. (Della Porta (Grail) Tr. 469-70). He further elaborated that the CIA Team tried to present information that was up to date. (Della Porta (Grail) Tr. 470).

3416. [redacted] (PX4075 (Grail) at 008 (Email from A. Aravanis, Grail, to M. Young, Grail, et al., attaching "Competitive Intelligence: An Overview," Sept. 7, 2019) (*in camera*)).

3417. Gautam Kollu, Grail's Chief Commercial Officer, shared competitive intelligence team slides with Grail's Board of Directors. (Della Porta (Grail) Tr. 469).

3418. In February 2019, Alex Aravanis, Grail's then-Chief Scientific Officer and Head of R&D, and Onaiza Cadoret-Manier, Grail's then-Chief Commercial Officer, presented a {[redacted]} (PX4046 (Grail) at 094 (Competitive Overview, Feb. 14, 2019) (*in camera*)).

3419. Reports from Grail's CIA team were shared with Grail's Board of Directors, finance teams, and investor relations teams. (Della Porta (Grail) Tr. 469).

3420. {[redacted]} (PX7069 (Bishop (Grail) IHT at 36) (*in camera*); *see, e.g.*, PX4129 (Grail) (Grail CIA Monthly Newsletter, Dec. 2020)).

3421. {[redacted]}

(PX4145 (Grail) at 008 (Competitive Intelligence, Aug. 14, 2019) (*in camera*) {[redacted]}).

3422. [redacted]

(PX4145 (Grail) at 047 (Competitive Intelligence, Aug. 14, 2019) (*in camera*); PX4075 (Grail) at 046 (Email from A. Aravanis, Grail, to M. Young, Grail, et al., attaching "Competitive Intelligence," Sept. 7, 2019) (*in camera*)).

3423. Mike Vicari, Grail's SVP of Sales, noted in an email that Grail's "legal team" uses the "type of information" provided by its CIA team to "[begin] looking at the side of patent infringement with all early stage companies in [Grail's] space." (PX4131 (Grail) at 001 (Email from M. Vicari, Grail, to Grail employees, Feb. 1, 2021)).

(2) Grail "CIA Team" Work Product Identifies Numerous Competitors to Grail and Galleri

3424. {[redacted]} (Della Porta (Grail) Tr. 503-04 (*in camera*)).

3425. {[redacted]} (PX4037 (Grail) at 008 [redacted] (*in camera*); PX4267 (Grail) at 012 [redacted] (*in camera*); PX4145 (Grail) at 006 (Competitive Intelligence, Aug. 14, 2019) (*in camera*); PX4048 (Grail) at 004 [redacted] (*in camera*); PX4350 (Grail) at 009 [redacted] (*in camera*)).

3426. {[redacted]} (Della Porta (Grail) Tr. 473 (*in camera*)).

3427. In a chart labeled {[redacted]} (PX4018 (Grail) at 006-07 [redacted] (*in camera*)). Grail's assessments {[redacted]} (PX4018 (Grail) at 006-07 [redacted] (*in camera*) ({[redacted]})).

3428. Grail identified {[redacted]} (PX4018 (Grail) at 005 [redacted] (*in camera*)).

3429. {[redacted]} (PX4259 (Grail) at 001 (Email from C. Della Porta, Grail, to J. Ofman, Grail, et al., Jul. 22, 2019) (*in camera*)).

3430. {[redacted]} (PX4259 (Grail) at 001 (Email from C. Della Porta, Grail, to J. Ofman, Grail, et al., Jul. 22, 2019) (*in camera*)). {[redacted]} (PX4259 (Grail) at 001 (Email from C. Della Porta, Grail, to J. Ofman, Grail, et al., Jul. 22, 2019) (*in camera*)).

3431. { } (Della Porta (Grail) Tr. 475 (*in camera*)).

3432. { } (PX4259 (Grail) at 001 (Email from C. Della Porta, Grail, to J. Ofman, Grail, et al., Jul. 22, 2019) (*in camera*)).

3433. { } (PX4037 (Grail) at 008 (*in camera*)).

3434. { } (PX4145 (Grail) at 009 (Competitive Intelligence, Aug. 14, 2019) (*in camera*)).

3435. In a May 2019 internal presentation labeled { } (PX4267 (Grail) at 009 (*in camera*)). Grail specifically { } (PX4267 (Grail) at 009 (*in camera*); *see also* PX4267 (Grail) at 009 (*in camera*) (chart tracking { }).

3436. { } (PX4075 (Grail) at 008 (Email from A. Aravanis, Grail, to M. Young, Grail, et al., attaching "Competitive Intelligence," Sept. 7, 2019) (*in camera*)). (Bishop (Grail) Tr. 1478-79 (*in camera*)).

3437. (PX4075 (Grail) at 046 (Email from A. Aravanis, Grail, to M. Young, Grail, et al., attaching "Competitive Intelligence," Sept. 7, 2019) (*in camera*)).

3438. In March 2020, Grail identified { } and noted that Grail { } (PX4450 (Grail) at 241-42 (*in camera*)).

3439. In an internal presentation about { } (PX4387 (Grail) at 043 (Galleri Commercial Approach, Q1 2020) (*in camera*)).

3440. { } (PX4093 (Grail) at 020 (Overview – ILMN) (*in camera*)).

3441. (PX4093 (Grail) at 020 (Overview – ILMN) (*in camera*)).

3442. { } (PX4093 (Grail) at 020 (Overview – ILMN) (*in camera*) (brackets in original)).

3443. (PX4093 (Grail) at 020 (Overview – ILMN) (*in camera*) (brackets in original)).

3444. (PX4284 (Grail) at 012 (Email from J. Ayers, W2O, to M. Burns, Grail, attaching "2020 Corporate Communications Plan," May 20, 2020) (*in camera*)).

3445. In June 2020, { } (PX4207 (Grail) at 013 (Competitive Intelligence Updates: Deep Dive, Jun. 9, 2020) (*in camera*)). { } (PX4207 (Grail) at 013 (Competitive Intelligence Updates: Deep Dive, Jun. 9, 2020) (*in camera*)). Grail's presentation included { } (PX4207 (Grail) at 013 (Competitive Intelligence Updates: Deep Dive, Jun. 9, 2020) (*in camera*)).

3446. { } (PX4554 (Grail) at 003 (*in camera*)).

3447. In an internal presentation dated August 17, 2020, Grail discussed { } (PX4052 (Grail) at 039 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)). { } (PX4052 (Grail) at 039 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

3448. In an internal presentation dated August 17, 2020, Grail identified { } (PX4052 (Grail) at 040 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)). { } (PX4052 (Grail) at 040 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

3449. As of August 2020, Grail identified { } (PX4052 (Grail) at 044 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)). { } (PX4052 (Grail) at 039 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

3450. As of August 17, 2020, Grail identified { } (PX4052 (Grail) at 045 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)). { } (PX4052 (Grail) at 039 (Grail Strategy Workshop #1, Aug. 17, 2020) (*in camera*)).

3451. An internal Grail presentation recognized { } (PX4016 (Grail) at 007 (Grail Strategy Planning Roadmap (Workshop #2), Sept. 2, 2020) (*in camera*)).

3452. { } (PX4048 (Grail) at 005 (*in camera*)). { }

} PX4048 (Grail) at 005 (*in camera*)).

3453. (PX4048 (Grail) at 005 (*in camera*)).

3454. (PX4016 (Grail) at 006 (Grail Strategy Planning Roadmap (Workshop #2), Sep. 2, 2020) (*in camera*)).

3455. (Della Porta (Grail) Tr. 510-12 (*in camera*); PX4444 (Grail) at 002 (*in camera*)).

3456. As a "Field Intelligence Update" from its "CIA Monthly Newsletter" for December 2020, Grail noted that it "anticipate[s] as Thrive (and future other competitors) get closer to launch, they will use tactics to sell against Grail." (PX4129 (Grail) at 002 (Grail CIA Monthly Newsletter, Dec. 2020)).

3457. Grail sent an (PX4337 (Grail) at 005-08 (*in camera*); PX4350 (Grail) at 001 (*in camera*)). Grail requested { } (PX4337 (Grail) at 006-07 (*in camera*)). } (PX4337 (Grail) at 005 (*in camera*)).

3458. In May 2021, Grail prepared a report on the 2021 AACR Conference. Twenty-seven Grail employees of Grail's Medical Affairs, Research & Development, and Bioinformatics groups are credited with contributing to the report. (PX4616 (Grail) at 007-09 (AACR 2021 Conference Report, May 5, 2021); Ofman (Grail) Tr. 3421-22 (*in camera*) [redacted].

3459. Grail's "Executive Summary: MCED" for its internal report on the 2021 AACR Conference states: "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 (AACR 2021 Conference Report, May 5, 2021)).

3460. Grail hired a company, Crayon, to "supplement and enhance [its] ongoing tracking of top competitors and key market trends such as sales related / launches, hiring and web page content changes, and executive/leadership changes, and to assist with report/summary generation." (PX4129 (Grail) at 001 (Grail CIA Monthly Newsletter, Dec. 2020); PX4059 (Grail) at 004 (Grail CIA Monthly Newsletter, Jan. 2021)). Grail's "CIA Monthly Newsletter" for January 2021 noted that Grail had started to work with Crayon to "create reports and battle cards." (PX4059 (Grail) at 004 (Grail CIA Monthly Newsletter, Jan. 2021)). Vicky Demas, Grail's Platform Product Manager and New Products Program Lead, provided [redacted] (PX4353 (Grail) at 003-04 (Email from V. Demas, Grail, to W. Cameron, Crayon, Dec. 23, 2020) (*in camera*)). Dr. Demas later explained in an email dated April 1, 2021: [redacted] (PX4359 (Grail) at 001-02 (Email from V. Demas, Grail, to D. Lockhead, Grail, et al., Apr. 1, 2021) (*in camera*)).

(3) [redacted]

3461. [redacted] (PX4250 (Grail) at 003 ([redacted] (*in camera*)).

3462. [redacted] (PX4250 (Grail) at 003, 009 ([redacted] (*in camera*)).

3463. [redacted]

} (PX4250 (Grail) at 009 ({ } (*in camera*)).

3464. (PX4250 (Grail) at 012 ({ } (*in camera*)).

(4) }

3465. (PX4049 (Grail) at 003 (Email from G. Kollu, Grail, to A. Chen, Grail, et al., July 24, 2020) (*in camera*)).

3466. In July 2020, Guatam Kollu wrote an email to other Grail executives (PX4049 (Grail) at 003 (Email from G. Kollu, Grail, to A. Chen, Grail, et al., July 24, 2020) (*in camera*)).

3467. { } (PX4049 (Grail) at 003 (Email from G. Kollu, Grail, to A. Chen, Grail, et al., July 24, 2020) (*in camera*)).

3468. } (PX4049 (Grail) at 001 (Email from S. Alag, Grail, to A. Chen, Grail, et al., July 28, 2020) (*in camera*)).

c) }

3469. Satnam Alag, Grail's Senior VP of Software Engineering and Chief Security Officer, wrote in a July 2020 email that { (PX4049 (Grail) at 002 (Email from S. Alag, Grail, to A. Chen, Grail, et al., July 24, 2020) (*in camera*)). {

[redacted]} (PX4049 (Grail) at 002 (Email from A. Chen, Grail, to S. Alag, Grail, et al., July 28, 2020) (*in camera*)).

3470. [redacted]} (PX4027 (Grail) at 002-03 (Email from M. Burns, Grail, to R. Currie, Grail, et al., July 30, 2020) (*in camera*)). [redacted] (PX4027 (Grail) at 001-02 (Email from D. Bhandari, Grail, to J. Ofman, Grail, et al., July 30, 2020) (*in camera*)).

d) [redacted]

(1) **Illumina Recognizes That Grail Competes with Illumina's Other NGS Customers**

3471. At the Cowen Liquid Biopsy Summit on September 21, 2020, Cowen analyst Doug Schenkel asked Francis deSouza, Illumina's CEO, how Illumina's customers are reacting to the Grail deal. (deSouza (Illumina) Tr. 2221-22; PX2575 (Illumina) at 064 (Email from T. Friedman, Illumina, to J. Cunningham, Illumina, attaching Illumina Inc at Cown Liquid Biopsy Summit Transcript, Sept. 29, 2020)). Mr. deSouza responded that, "in a few segments we will provide a vertical solution that could compete with some of our customers." (deSouza (Illumina) Tr. 2221-22; PX2575 (Illumina) at 065 (Email from T. Friedman, Illumina, to J. Cunningham, Illumina, attaching Illumina Inc at Cowen Liquid Biopsy Summit Transcript, Sept. 29, 2020)).

3472. 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)).

3473. [redacted]

[redacted] (deSouza (Illumina) Tr. 2251-2253 (*in camera*); PX2569 (Illumina) at 008 (Executive Session, Apr. 28, 2020) (*in camera*)).

3474. [redacted] } (Berry (Illumina) Tr. 938 (*in camera*)). { [redacted] } (Berry (Illumina) Tr. 938 (*in camera*)).

3475. Illumina identified "Guardant, Freenome, and Foundation Medicine" as "companies [that] were interested in early detection" of cancer and proactively reached out to them post-merger to discuss a proposed supply agreement. (deSouza (Illumina) Tr. 2429).

3476. [redacted] } (deSouza (Illumina) Tr. 2250-51 (*in camera*); PX2549 (Illumina) at 021 (Board of Directors Meeting, Apr. 28, 2020) (*in camera*)).

3477. [redacted] (PX2009 (Illumina) at 019 (Email from J. Goswami, Illumina, to M. Nguyen, Illumina, et al., attaching April BoD M&A Strategy Presentation, Apr. 14, 2020) (*in camera*)).

3478. [redacted] (PX2009 (Illumina) at 019 (Email from J. Goswami, Illumina, to M. Nguyen, Illumina, et al., attaching April BoD M&A Strategy Presentation, Apr. 14, 2020) (*in camera*)).

3479. { [redacted] (PX2013 (Illumina) at 010 (Science & Technology Committee Cancer Screening, Apr. 28, 2020) (*in camera*)).

3480. Illumina noted in a Thrive company overview presentation that Thrive's CancerSeek test is a "multi-cancer competitor to project Valor." (PX2054 (Illumina) at 003 (MCED Company Overview Presentation) [redacted]

3481. Illumina noted in a Guardant Health company overview slide that Guardant is a "[c]ompetitor to project Valor [and a] [k]ey [c]ustomer." (PX2054 (Illumina) at 001 (MCED Company Overview Presentation) [redacted]

3482. Illumina noted on a Freenome overview slide that Freenome is a "[c]ompetitor to project Valor." (PX2054 (Illumina) at 005 (MCED company overview presentation) [redacted]

(2) [redacted]

3483. [redacted] (*See* Bishop (Grail) Tr. 1500-01 (*in camera*); PX4476 (Grail) at 002 [redacted] (*in camera*)).

3484. [redacted] (PX4476 (Grail) at 004 [redacted] (*in camera*); Bishop (Grail) Tr. 1507-08) (*in camera*)).

3485. [redacted] (PX4473 (Grail) at 003 (Core Team, Apr. 15, 2021) (*in camera*) (*see* inset image).

[redacted]

{ }

3486. [redacted] } (PX4473 (Grail) at 012 (Core Team, Apr. 15, 2021) (*in camera*)). { [redacted] (PX4473 (Grail) at 012 (Core Team, Apr. 15, 2021) (*in camera*)).

3487. [redacted] (PX4476 (Grail) at 002 [redacted] (*in camera*)).

3488. [redacted] (PX4476 (Grail) at 004 [redacted] (*in camera*)).

3489. [redacted] (PX4476 (Grail) at 004 [redacted] (*in camera*)).

3490. [redacted] } (PX4473 (Grail) at 005 (Core Team, Apr. 15, 2021) (*in camera*)).

3491. [redacted] } (PX4473 (Grail) at 005 (Core Team, Apr. 15, 2021) (*in camera*)).

3492. [redacted] } (PX4476 (Grail) at 004 [redacted] (*in camera*)).

3493. [redacted]

} (*See* PX7077 (Chahine (Helio) Dep. at 30-32) (*in camera*)).

2416 (Singlera);

3494.

3495.

3496.

} (*in camera*)).

3497.

}

f) Expert Analysis Confirms That the Acquisition Gives Illumina the Incentive and Ability to Disadvantage MCED Test Developers That Compete with Grail

3498. {

} (*See* PX6090 (Scott Morton Report) ¶ 177 (*in camera*)).

3499. Dr. Scott Morton concluded that the combination of Illumina and Grail gives Illumina the incentive and ability to anoint Grail the winner in the MCED test innovation race. (PX7138 (Scott Morton Trial Dep. at 19-20)).

3500. [redacted] (PX7138 (Scott Morton Trial Dep. at 85) (*in camera*)).

3501. [redacted] (PX7138 (Scott Morton Trial Dep. at 57) (*in camera*)).

3502. [redacted] (PX7138 (Scott Morton Trial Dep. at 61-62, 656) (*in camera*)).

3503. [redacted] (PX7138 (Scott Morton Trial Dep. at 31-32) (*in camera*); *see also* PX6090 (Scott Morton Report) ¶ 172 (*in camera*) ([redacted])).

3504. [redacted] PX7138 (Scott Morton Trial Dep. at 48) (*in camera*)).

3505. [redacted] (PX7138 (Scott Morton Trial Dep. at 54-55) (*in camera*)).

3506. [redacted] PX7138 (Scott Morton Trial Dep. at 57) (*in camera*)).

3507. [redacted] (PX7138 (Scott Morton Trial Dep. at 358) (*in camera*)).

4. Patients Will Use a Single MCED Test for Screening

3508. At trial, Bill Getty, Guardant's SVP of Commercial, Cancer Screening Core, testified that he expects primary care physicians choosing between Galleri or LUNAR-2 tests would order one for their patients, not both. (Getty (Guardant) Tr. 2675).

3509. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 177-178) (*in camera*)).

3510. Mr. Nolan, Freenome's CEO, testified at trial that he does not expect primary care providers to use more than one MCED test simultaneously: "I think when there's a multicancer option I think [primary care providers will] choose one and not, you know, go back and forth between one and the other. Once they actually implement one multicancer test, I believe they'll stick with that for standardization of process and test results interpretation." (Nolan (Freenome) Tr. 2727-28).

3511. Respondents' expert, Dr. Abrams, testified at trial that he expects to order no more than one MCED test per patient at a time. (Abrams Tr. 3643). More specifically, Dr. Abrams explained that he does not expect to order both Grail's Galleri and Exact's CancerSEEK simultaneously for patients. (PX7137 (Abrams, Dep. at 82-83)).

3512. [redacted] (PX6097 (Abrams Rebuttal Report) ¶ 33 (*in camera*)).

3513. [redacted] (PX6097 (Abrams Rebuttal Report) ¶ 33 (*in camera*)).

3514. Dr. Abrams testified that the best MCED test for a given patient may depend on a patient's risk factors. (PX7137 (Abrams Dep. at 84)).

3515. Dr. Abrams admits that he is "not the least bit reticent to make a change if a new test is superior to the existing." (PX7137 (Abrams Dep. at 85-86)).

5. MCEDs Will Compete on Various Product Features

3516. Grail's CEO, Hans Bishop, testified that, whereas Grail has chosen to focus on cfDNA methylation, other companies have chosen to focus on protein analysis and others on multiomics that "combin[e] those different modalities." (PX7069 (Bishop (Grail) IHT at 154-56)).

3517. Mr. Bishop explained that there are a "number of different approaches different companies are taking," including multiomics as a way to try "to get to the highest-performing technology." (PX7069 (Bishop (Grail) IHT at 154-56)).

3518. Mr. Bishop testified that patients benefit from having multiple MCED tests in development. (*See* PX7069 (Bishop (Grail) IHT at 154-56)).

3519. Mr. Bishop testified that "one of the exciting things about the horizon scanning [Grail] do[es] and the field in general is the number of different approaches different companies are taking." (PX7069 (Bishop (Grail) IHT at 154-56)).

3520. Mr. Bishop testified that "difficult problems are, by definition, hard to solve, and having a multitude of different approaches is a good thing." (PX7069 (Bishop (Grail) IHT at 154-56)).

3521. [redacted] (Della Porta (Grail) Tr. 478-79 (*in camera*)).

3522. [redacted] (PX7087 (Goswami (Illumina) Dep. at 122-123) (*in camera*)).

3523. With respect to technologies used for cancer detection, Dr. Bert Vogelstein, 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, testified that "[t]here are many different analytes that can be detected in blood, many different characteristics of DNA, and I don't know which will be superior because no one, including Thrive or us that I know of, has yet done the kinds of studies that will indicate which tests will be superior in actual practice in a prospective trial." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 48-49)).

3524. [redacted]

3525. [redacted]

[redacted]

3526. [redacted]

3527. [redacted]

3528. [redacted] (*in camera*)).

3529. Respondents' economic expert, Dr. Carlton, conceded that differentiated products can be substitutes:

> Q. And you agree, as a general matter, that differentiated products can be substitutes depending on the cross elasticity of demand by consumers, right?
>
> A. I think I put it a little differently, that products that are differentiated can have – it can be substitutes, in part, but they won't be as substitutable as if they were identical. But just because you're not identical doesn't mean there's no substitution. That, I agree with.

(PX7134 (Carlton Dep. at 134-35)).

3530. Respondents' economic expert, Dr. Katz, admitted that a properly defined relevant product market can include differentiated products. (PX7145 (Katz Dep. at 47)).

3531. Respondents' expert, Dr. Katz, testified that part of R&D competition was differentiating a firm's product to compete on different product features or functions. (RX6004 (Katz Trial Dep. at 106)).

3532. Respondents' expert, Dr. Katz, testified that he understood that different MCED test developers have taken different approaches to developing their MCED tests. (RX6004 (Katz Trial Dep. at 106-107)). For example, different MCED test developers are

developing tests that analyze different types of biomarkers. (RX6004 (Katz Trial Dep. at 107)).

3533. Grail's 2021 AACR Conference Report states: "Methylation is not the only methodology, and several [other companies] combine this approach with others." (PX4616 (Grail) at 017 (AACR 2021 Conference Report, May 5, 2021)).

a) The Number of Cancers an MCED Test Screens for is One of Many Factors on which Tests Will Compete

(1) No Test Has Been Clinically Shown to Screen for More than Ten Cancers in an Asymptomatic Population

For evidence that no test has been clinically shown to screen for more than ten cancers in an asymptomatic population, see Section X, Appendix B (Galleri Has Not Been Clinically Shown to Provide Early Detection of More Than 50 Cancers in an Asymptomatic Population).

(2) Other MCED Developers Are Planning to Add Cancers Over Time

For additional evidence of how some MCED test developers plan to add cancers to their existing MCED test technological platform, see Section VII.B.3.e. (NGS-Based Single Cancer Tests Are an Initial Step Towards Development of MCED Tests).

3534. [redacted]

3535. [redacted]

3536. [redacted]

3537. [redacted]

3538. [redacted]

3539. Singlera's PanSeer test is currently focused on screening for colorectal, lung, gastric, esophageal, and liver cancers, but it is designed to detect any kind of cancer. (*See* PX7042 (Gao (Singlera) IHT at 28-30)).

3540. [redacted]

3541. [redacted]

3542. Dr. Chahine testified that Helio plans to add additional cancers to its test for early detection of liver cancer and to later launch the test as an MCED test. (Chahine (Helio) Tr. 1000-01).

3543. [redacted]

3544. Helio has told its investors that it intends to develop an MCED test by adding additional cancers to its single-cancer liver test. (Chahine (Helio) Tr. 1037-38).

3545. [redacted]

b) The Ability to Identify Tissue of Origin is One of Many Factors on Which Tests Will Compete

3546. [redacted]

3547. As Respondents' own expert Dr. Richard Abrams testified, the exact number of cancers is just one factor that might cause him to switch between MCED tests, with accuracy being "first and foremost" the most important factor, along with other factors like price and tissue of origin capabilities. (Abrams Tr. 3632-33).

(1) [redacted]

3548. [redacted]

3549. [redacted]

3550. [redacted]

3551. [redacted]

3552. [redacted]

3553. [redacted]

3554. [redacted]

3555. [redacted]

3556. Singlera's PanSeer test is designed to detect tissue of origin. (Gao (Singlera) Tr. 2874).

(2) Tests Have Taken Alternative Approaches to TOO

3557. [redacted]

3558. [redacted]

3559. [redacted]

3560. [redacted]

3561. [redacted]

[redacted]

[redacted]

3562. [redacted]

3563. [redacted]

3564. [redacted]

(3) Grail's MCED Test Will Require Additional Scanning

3565. Grail's CEO, Hans Bishop, testified at trial that certain patients may undergo a body scan to identify the cancer tissue of origin. (Bishop (Grail) Tr. 1387).

3566. Grail's CEO, Hans Bishop, testified that "ultimately patients will then get a biopsy, but that step needs . . . to have a diagnostic confirmation." (Bishop (Grail) Tr. 1387).

3567. Galleri does not predict tumor of origin for fifty cancer types. (Ofman (Grail) Tr. 3433). As Dr. Ofman testified, for colon and rectum cancers, Galleri predicts a single tissue of origin, rather than five cancer types. (Ofman (Grail) Tr. 3434). Dr. Ofman elaborated that the tissue of origin classifier is grouped into 24 categories. (Ofman (Grail) Tr. 3453).

3568. [redacted] (PX4207 (Grail) at 040 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (*in camera*)). [redacted] (PX4207 (Grail) at 040 (Competitive Intelligence Updates: Deep Dive, June 9, 2020) (*in camera*)).

3569. Respondents' expert, Dr. Richard Cote, testified at trial that a physician may need to perform a targeted follow-up screening test on individuals who take the Galleri test. (Cote Tr. 3802-3803).

C. HARM TO GRAIL'S RIVALS WILL LEAD TO DECREASED INNOVATION IN THE U.S. MCED TEST MARKET

3570. Respondents' own expert, Dr. Carlton, testified that harm to innovation is "a concern you should worry about" when examining the effects of a merger. (PX7134 (Carlton Dep. at 82-83)). Additionally, Respondents' expert, Dr. Katz, testified that if innovation is "stifled," "that would be in my view a bad thing." (PX7145 (Katz Dep. at 39-41)).

3571. [redacted] (PX7138 (Scott Morton Trial Dep. at 32) (*in camera*)).

3572. [redacted] (PX7138 (Scott Morton Trial Dep. at 32-33) (*in camera*)).

3573. [redacted] (PX6090 (Scott Morton Report) ¶¶ 171-73 (*in camera*)).

3574. Dr. William Cance, Chief Medical and Scientific Officer of the American Cancer Society, testified that "multiple companies and institutions developing and improving [MCED] technology is very important." (PX7086 (Cance (American Cancer Society) Dep. at 100-101)).

3575. Respondents' own expert, Dr. Richard Abrams, testified, "if there are multiple laboratories and companies developing better and better products, that would be a great advantage to me as a physician and, most importantly, to my patients." (PX7137 (Abrams Dep. at 73)). Dr. Abrams testified that one way MCED tests will "get better and better" is through competition among multiple companies, adding that "[c]ompetition is America." (PX7137 (Abrams Dep. at 75-76)).

3576. As the CEO of Freenome explained, he is "focused on beating the competitor, which is cancer," and "there's room for a lot of folks if we take that approach and that we have a fair and level playing field to achieve it." (Nolan (Freenome) Tr. 2727).

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

3577. [redacted] (PX6090 (Scott Morton Report) ¶¶ 155-56 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶ 156 (*in camera*)).

3578. [redacted] (PX6090 (Scott Morton Report) ¶ 156 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶ 157 (*in camera*)).

3579. [redacted] (PX6090 (Scott Morton Report) 160 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶ 160 *(in camera*)).

3580. [redacted] (PX6090 (Scott Morton Report) ¶ 159 (*in camera*)).

3581. [redacted] (PX7138 (Scott Morton Trial Dep. at 31-32) (*in camera*)).

3582. [redacted] Gao (Singlera) Tr. 2888-2889; [redacted]

3583. {[redacted]} (PX7053 (Fesko (Natera) IHT at 28) (*in camera*)).

3584. Singlera spends approximately $30 million annually on research and development. (PX7042 (Gao (Singlera) IHT at 22)).

3585. Singlera's Dr. Gao testified at trial 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).

3586. Singlera is working to "reduce cost, improve accuracy, and improve convenience" of its test. (PX7042 (Gao (Singlera) IHT at 100).

3587. [redacted]

3588. [redacted]

3589. [redacted]

3590. [redacted]

3591. {[redacted]

3592. [redacted]

[redacted] (PX4250 (Grail) at 012 ({ }) (*in camera*)). [redacted] (PX4054 (Grail) at 004 [redacted] (*in camera*)).

3593. {[redacted]

[redacted]

}

(PX6090 (Scott Morton Report) ¶ 161 (*in camera*)).

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

3594. Dr. Scott Morton testified that Illumina's acquisition of GRAIL will deprive consumers of the benefits from the scientific activity and investment involved in the race to develop an MCED test. (PX7138 (Scott Morton Trial Dep. at 20)).

3595. [redacted]
(PX7138 (Scott Morton Trial Dep. at 82) (*in camera*)).

3596. [redacted] } (PX7138 (Scott Morton Trial Dep. at 82-83) (*in camera*)).

3597. Further, Dr. Scott Morton concluded in her report that {[redacted] (PX6090 (Scott Morton Report) ¶ 12 (*in camera*)).

3598. According to Illumina's former CEO and board member Jay Flatley, 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)).

3599. According to Mr. 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)).

3600. [redacted] (PX7105 (Getty (Guardant) Dep. at 72-73) (*in camera*)). 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 33)).

3601. The cost of producing an MCED test is "highly indexed" to the cost of sequencing. (Getty (Guardant) Tr. 2518).

3602. Dr. Gao, Board Member, 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)).

3603. [redacted] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 194) (*in camera*)).

3604. [redacted] } (PX8324 (Roche) at 005 [redacted] (*in camera*)).

3605. [redacted] } (PX8324 (Roche) at 005 [redacted] (*in camera*)).

3606. Helio's Chahine warned, "if investors see this as a foregone conclusion that Grail and Illumina are going to win the [MCED test development] category and investment dries up, then absolutely, it could have negative consequences for innovation in the category." (PX7077 (Chahine (Helio) Dep. at 62)).

3607. Mr. Chahine elaborated:

[redacted]

[redacted]

(PX7077 (Chahine (Helio) Dep. at 56) (*in camera*)).

3608. Guardant's Mr. Getty stated that the company is "in a bit of a freeze because if you believe [Illumina] [is] going to, you know, increase your price across your portfolio, then the question becomes why, why would you pursue future tests. You know, there's no way to be successful there. So it -- unfortunately, the acquisition largely slows down innovation not just at Guardant but across the entire industry because everyone else is just as reliant on Illumina as well." (PX7040 (Getty (Guardant) IHT at 147)).

3609. Further, Mr. Getty warned that one implication of Illumina's acquisition of Grail was that:

> [I]n a more sort of nefarious potential, you have a competitor who controls essentially your margins, and so, you know – and they – and internally Illumina obviously, you know, wants the most profitable product and can do things at a lower cost because they are the manufacturer of the reagent, and so not only could they copy what we were doing, they could do it at a lower cost, maximize their own profitability, and slowly squeeze us into a position of being completely uncompetitive or, you know, *potentially not able to support the innovation that we would need or the innovation we'd want to pursue*.

(PX7040 (Getty (Guardant) IHT at 135) (emphasis added)).

3610. 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)).

3611. 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)).

3612. 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 76)).

3613. [redacted]

3614. [redacted]

[redacted]

3615. [redacted]

3616. [redacted]

[redacted]

3617. [redacted]

3618. [redacted]

3619. [redacted]

[redacted]

[redacted]

3620. [redacted]

[redacted]

3621. [redacted]

[redacted]

3622. Singlera's Dr. Gao testified at trial that he is concerned about the impact of Illumina's acquisition of Grail on Singlera's ability to raise money from investors. (Gao (Singlera) Tr. 2902).

3623. Dr. Gao explained how Singlera's negotiations with Illumina could impact investment in Singlera: "Illumina will now play hardball for negotiation, and that either will take us longer time to negotiate or even convince any investor this is worthy, economically, you know, feasible. I think we will be at a disadvantage to convince any investor to invest in us." (PX7042 (Gao (Singlera) IHT at 130)).

3624. According to Dr. Gao, an inability to raise money from investors will be "very damaging" to Singlera, as the company would have to "lay off people, and then maybe narrow down other things." (Gao (Singlera) Tr. 2902).

3625. Dr. Gao testified, "[t]here's no incentive for Illumina to support . . . people other than GRAIL." (PX7042 (Gao (Singlera) IHT at 90)).

3626. Dr. Gao elaborated, Illumina will have "no incentive to faithfully negotiate with anyone, not only Singlera, on how their machine will be used or priced." (PX7042 (Gao (Singlera) IHT at 130)).

3627. [redacted]

3628. [redacted]

3629. [redacted]

3630. [redacted]

3631. [redacted]

3632. [redacted] (Lengauer (Third Rock Ventures) Tr. 196-99 (*in camera*)).

3633. [redacted]

[redacted]

(Lengauer (Third Rock Ventures) Tr. 197-98 (*in camera*)).

3634. [redacted]
(PX7051 (Lengauer (Third Rock Ventures) IHT at 92-93. 189-91) (*in camera*)).

3635. [redacted] (Lengauer (Third Rock Ventures) Tr. 98 (*in camera*)).

3636. [redacted] (Lengauer (Third Rock Ventures) Tr. 200 (*in camera*)).

3637. [redacted] (Lengauer (Third Rock Ventures) Tr. 196-99 (*in camera*)).

3638. [redacted] (PX7091 (Lengauer (Third Rock Ventures) IHT at 257-58) (*in camera*)).

For additional evidence on MCED test developers concerns with the Illumina-Grail transaction, see Section VIII.A.2.c. (Concerns Regarding Illumina's Acquisition of Grail Expressed by Illumina Customers).

2. MCED Developers Are Currently Competing—and Expect to Continue to Compete—on the Basis of Innovation, Not Just Price

3639. [redacted] (PX7138 (Scott Morton Trial Dep. at 30) (*in camera*)).

3640. [redacted] (PX7138 (Scott Morton Trial Dep. at 352) (*in camera*)).

3641. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 16 (*in camera*)).

3642. [redacted] (RX6004 (Katz Trial Dep. at 105) (*in camera*)).

3643. As Chief Medical and Scientific Officer for the American Cancer Society, Dr. William Cance, explained, "I don't believe we will have one test be 100 percent accurate and zero percent inaccurate. So, therefore, multiple companies and institutions developing and improving this technology is very important." (PX7086 (Cance (American Cancer Society) Dep. at 101)).

3644. [redacted] *see also* PX7105 (Getty (Guardant) Dep. at 42) (testifying that Guardant "will do what [it has] always done, which is improve the performance of [its] assay in order to remain competitive")).

a) Despite Grail's First-Mover Advantage, Other MCED Developers Will Have the Incentive to "Leapfrog" Grail by Offering Better Technology

3645. [redacted]

(PX6090 (Scott Morton Report) ¶ 222 (*in camera*)).

3646. [redacted] (Bishop (Grail) Tr. 1447-48 (*in camera*); PX7083 (Bishop (Grail) Dep. at 70-71)).

3647. Grail CEO, Hans Bishop, emphasized that "one of the exciting things about the horizon scanning we do and the [MCED test development] field in general is the number of different approaches different companies are taking." (PX7069 (Bishop (Grail) IHT at 154-156)).

3648. Mr. Bishop explained that there are a "number of different approaches different companies are taking," including multiomics as a way to try "to get to the highest-performing technology." (PX7069 (Bishop (Grail) IHT at 154-56)).

3649. Grail previously pursued other approaches to detecting cancer, including mutations and aneuploidy in cfDNA, but later decided to focus on the use of methylation sites in cfDNA as its method for the Galleri test. (PX4082 (Grail) at 099 (Email from B. Cornelius, Latham & Watkins LLP, to C. Gartin, Morgan Stanley, et al., attaching Grail 2020 S-1/Amended, Sept. 17, 2020); PX7069 (Bishop (Grail) IHT at 123-24)).

3650. Dr. William Cance, Chief Medical and Scientific Officer of the American Cancer Society declared:

> Having multiple approaches to compare against one another can ultimately lead to better clinical outcomes for patients and more cost-effective approaches to cancer detection for the benefit of patients. A good example of the importance of multiple approaches to innovation is the development and efficacy of COVID vaccinations from Pfizer, Moderna, Johnson & Johnson, AstraZeneca, Novavax, and others. At this stage, it is unclear whether analyzing DNA mutations, DNA methylation patterns, chromosomal variations, 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)).

3651. [redacted] (PX6090 (Scott Morton Report) ¶ 160 (*in camera*)).

3652. In testimony, Dr. Vogelstein affirmed,

> Researchers and ultimately the public benefit from having multiple firms and companies developing tests employing nucleic acid sequencing for the earlier detection of cancer. The greater the number of teams of researchers working with nucleic acid sequencing technologies such as Illumina's to identify cancer-specific differences in nucleic acids in the blood, the greater the chances of new

> discoveries that lead to more accurate, more effective, and more cost-effective earlier detection tests being developed.

(PX7101 (Vogelstein (Johns Hopkins University) Dep. at 71)).

3653. With respect to which technology will be most successful for detecting cancer in blood, Dr. Vogelstein testified that he has "a sense it will be based on massively parallel sequencing" but other than that he doesn't know which will be most successful because "there's so many analytes and ways of analyzing cell-free DNA using massively parallel sequencing." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 80-81)).

3654. With respect to technologies used for cancer detection, Dr. Vogelstein testified that "[t]here are many different analytes that can be detected in blood, many different characteristics of DNA, and I don't know which will be superior because no one, including Thrive or us that I know of, has yet done the kinds of studies that will indicate which tests will be superior in actual practice in a prospective trial." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 48-49)).

3655. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 179) (*in camera*)).

3656. [redacted] (PX7051 (Lengauer (Third Rock Ventures) IHT at 179) (*in camera*)).

3657. [redacted] } (PX7051 (Lengauer (Third Rock Ventures) IHT at 179) (*in camera*)).

3658. [redacted] } (PX7058 (Conroy (Exact) IHT at 114-15) (*in camera*)).

3659. [redacted] } (Conroy (Exact) Tr. 1558-59 (*in camera*)).

3660. [redacted] (Conroy (Exact) Tr. 1558-59 (*in camera*)).

3661. Singlera's Dr. Gao testified that "continuous improvement, innovation, to reduce cost, improve accuracy and improve convenience will always be [ ] nonstop of any company." (PX7042 (Gao (Singlera) IHT at 100)).

3662. Dr. Gao elaborated that innovation is "the number one [priority for Singlera's executives], the soul of our company" because Singlera "ha[s] to innovate to survive" as a company. (PX7042 (Gao (Singlera) IHT at 100-01)).

3663. [redacted]

3664. [redacted]

3665. [redacted]

3666. Guardant plans to differentiate its own MCED test from others based on the company's "legacy of innovation" being the "first liquid biopsy to be approved by the FDA in a different context but in the context of treatment selection." (PX7105 (Getty (Guardant) Dep. at 41)).

3667. Bill Getty, Senior Vice President of Commercial at Guardant, emphasized that Guardant "will do what [it has] always done, which is improve the performance of [its] assay in order to remain competitive." (PX7105 (Getty (Guardant) Dep. at 41-42)).

3668. Mr. Getty elaborated that Guardant's focus on improving the performance of its MCED test will in turn provide "greater benefit for patients and also is a compelling value of proposition to physicians." (PX7105 (Getty (Guardant) Dep. at 41-42)).

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

1. Illumina Identified Tools When It Launched and Spun Off Grail

a) When Illumina Created a Grail as a Majority-Controlled Entity, Illumina Gave Grail Exclusive Discounts and Special Assistance

(1) Illumina Created Grail as an Independent Company That Was Majority Owned by Illumina

3669. The team that started Grail began work on Grail in 2015 as a part of Illumina. (deSouza (Illumina) Tr. 2194-95).

3670. Illumina executives explained that Grail was separately incorporated in the beginning of 2016. (deSouza (Illumina) Tr. 2194-95); Flatley (Illumina) Tr. 4090)).

3671. Grail remained an Illumina-affiliated entity after it was incorporated. (deSouza (Illumina) Tr. 2198-99; Flatley (Illumina) Tr. 4092; *See also* PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 8 (RFA No. 5)).

3672. "Illumina admits that it formed GRAIL in January of 2016, and at that time held a majority of the voting shares of GRAIL." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 8 (RFA No. 5)).

3673. Illumina prepared questions and answers relating to the formation of Grail for "a presentation to investors about GRAIL and what [Illumina was] doing in forming GRAIL." (PX2543 (Illumina) (Illumina, GRAIL FAQs, Jan. 11, 2016); deSouza (Illumina) Tr. 2196-97).

3674. The presentation Illumina prepared for investors explains that "Illumina [is] starting another company vs. expanding its own business to include these new services" because Grail was a major R&D endeavor "requiring trials which will sequence more individuals than any program announced to date, but with the potential for significant returns." (PX2543 (Illumina) at 001-02 (Illumina, GRAIL FAQs, Jan. 11, 2016); deSouza (Illumina) Tr. 2195-96).

3675. The presentation Illumina prepared for investors notes that "GRAIL is majority owned by Illumina, but the independent company structure will allow [them] to run as a true start-up." (PX2543 (Illumina) at 002 (Illumina, GRAIL FAQs, Jan. 11, 2016)).

3676. The presentation Illumina prepared for investors notes that "[t]he business of GRAIL will be very different than Illumina's core business." (PX2543 (Illumina) at 002 (Illumina, GRAIL FAQs, Jan. 11, 2016)).

(2) At the Time It Created Grail, Illumina Purposefully Avoided Focusing on Overlapping Markets With Its Customers

3677. Jay Flatley – then the CEO of Illumina – explained to Jeff Huber that when forming Grail, "[i]n order to avoid competition with Illumina customers already focused on determining tumor mutational status from a draw (liquid biopsies), minimal residual disease, or therapeutic response monitoring, Python [Grail] will focus entirely on asymptomatic individuals." (PX2218 (Illumina) at 001 (Email from J. Flatley, Illumina, to J. Huber, Illumina, Feb. 22, 2016).

3678. Mr. Flatley also explained to Mr. Huber that when forming Grail, "[i]n order to avoid competition with Illumina customers already focused on cancer risk testing (e.g. BRCA testing), Python [Grail] will focus on the detection of somatic mutations in ctNDA and ctRNA rather than on inherited mutations in tissues." (PX2218 (Illumina) at 001 (Email from J. Flatley to J. Huber, Feb. 22, 2016).

3679. Mr. Flatley testified that if Grail competed "in markets that already existed, then customers wouldn't want to participate in those markets because they'd believe that Illumina could always underprice them if we wanted to." (PX7057 (Flatley (Illumina) IHT at 166–68)).

(3) While Illumina Had Majority-Ownership, Grail Received Preferential Treatment

(a) Grail's Supply Agreement with Illumina Included Significant Discounts

3680. While Illumina was the majority owner, Grail had access to deeper discounts on Illumina consumables and instruments than other Illumina customers. (deSouza (Illumina) Tr. 2198-99).

3681. [redacted] } (PX2550 (Illumina) at 001, 037 [redacted]

3682. [redacted] } (PX2550 (Illumina) at 001, 008–09, 038 [redacted] (*in camera*); *see also* PX2183 (Illumina) at 004 (Email from N. Naclerio, Illumina, to A. Pierce, Illumina, et al., attaching Python: Board Approval, Dec. 20, 2015)).

3683. [redacted] (PX7079 (Flatley (Illumina) Dep. at 132) (*in camera*)). (*See also* PX2712 (Illumina) at 042 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, attaching Illumina, Python Update, Dec. 12, 2015) ("Discount on Illumina products: 75% (with MFN) discount from list price on select products for us in the Python Field")).

3684. [redacted] (PX2553 (Illumina) at 062 (Illumina, GRAIL Financial Update, Oct. 26, 2016) (*in camera*)).

3685. By the end of 2015, Illumina recognized that the "[c]ost of sequencing" and "[c]linical validation and utility evidence" were two of the "[m]ost significant barriers and drivers of liquid biopsy innovation and adoption." (PX2557 (Illumina) at 032 (Illumina, Minutes of the Meeting of the Board of Directors of Illumina, Inc., Dec. 20, 2015)).

3686. A 2015 Illumina document stated: "our unique advantage is that we can sequence at depths today that would be cost-prohibitive to others" and that Illumina thus had "the technology and cost structure to do [ultra-deep sequencing to detect ctDNA] years before anyone else." (PX2005 (Illumina) at 005 (Illumina, ScreenCo: Early Cancer Detection on a Global Scale, 2015)).

3687. Illumina regarded the discounts to Grail as "forward pricing"—lower pricing based on where Illumina expected pricing to be "two or three years" or more into the future. (PX7089 (Naclerio (Illumina) Dep. at 250-251) (acknowledging that Grail's initial agreements with Illumina involved forward pricing and defining the term); PX2412 (Illumina) at 007 (Email from J. Flatley, Illumina, to J. Bird, Sutter Hill Ventures, attaching Project Python: Summary of Key Commercial Terms, Dec. 19, 2015) (discussing the exclusivity provision between Illumina and Grail from paragraphs 2.19 to 2.19.b.v.)).

3688. Illumina expected that the "Special Pricing" Illumina gave to Grail in the 2016 supply and commercialization agreement would result in "~$100M savings" to Grail "over [the] first 3 years[.]" (PX2183 (Illumina) at 004 (Email from N. Naclerio, Illumina, to A. Pierce, Illumina, et al,, attaching Python: Board Approval, Dec. 20, 2015)).

3689. A 2016 Grail presentation to Illumina's board contained a slide titled "GRAIL Moats: Why We Can Do This and Others Can't." One reason listed was "Economic advantage for product development/clinical plans enabled by Illumina equipment & reagent discount (~$350M value vs. retail through 2021)." (PX4044 (Grail) at 025 (Email from J. Huber, Grail, to R. Nelsen, Illumina, et al, attaching GRAIL Illumina BoD Update, Oct. 27, 2016)).

3690. Dr. Aravanis explained this special pricing enabled Illumina "to have early research and development happen sooner." (PX7065 (Aravanis (Illumina) IHT at 37)).

3691. Dr. Aravanis further explained that this special pricing enabled Grail's work." (PX7065 (Aravanis (Illumina) IHT at 39)).

3692. Dr. Naclerio testified that it would have been difficult for Grail to develop its MCED test without forward pricing. (PX7060 (Naclerio (Illumina) IHT at 201-02)).

(b) Illumina's Discounts to Grail as an Affiliated Entity Were Exclusive

3693. At the time of Grail's formation, Grail had no competitors, as "ctNA companies [were] currently focused in therapy selection [and were] not yet pursing screening." (PX2554 (Illumina) at 014 (Email from J. Owens, Illumina, to P. Scagnetti, Illumina, et al., attaching Illumina, Python Board Slides, Oct. 26, 2015); *see also* PX2543 (Illumina) at 001 (Illumina, GRAIL FAQs, Jan. 11, 2016) ("We do not believe GRAIL is competing with the customers we're enabling in the liquid biopsy space. We don't believe any of our customers have the ability to economically deploy this test in the next five years, due to the scale of clinical trial work required."); PX7060 (Naclerio (Illumina) IHT at 172-73) (explaining that at the time Grail first started exploring the option of starting Grail, there were not "any companies who had quite the audacious goal of saying let's – let's go right to screening asymptomatic people for cancer."); PX7107 (deSouza (Illumina) Dep. at 182) (explaining that he was "not aware of any" Grail competitors "at that time")).

3694. Illumina, however, already recognized the potential for competition between Grail and cancer detection test developers that would likely seek to develop an early detection test but would need Illumina's NGS platform to do so. In valuing Grail, Dr. Nick Naclerio—at the time Illumina's Senior Vice President of Corporate and Venture Development—

described Illumina as "giving NewCo [Grail] a (time bounded) monopoly." (PX2026 (Illumina) at 002 (Email from N. Naclerio, Illumina, to R. Klausner, Illumina, and M. Stapley, Illumina, Aug. 19, 2015)).

3695. In another email related to valuing Grail, Dr. Naclerio noted that Illumina "should also footnote that this model assumes that we have not forgone any revenue over the next 8 years by exclusively enabling Python for this market. If we assume that others (FMI, Natera, Guardant, etc) would have purchased instruments and reagents to go after the same opportunity had we not partnered exclusively with Python, we should net that out from our upside[.]" (PX2043 (Illumina) at 001 (Email from N. Naclerio, Illumina, to J. Owens, Illumina, and P. Scagnetti, Illumina, Oct. 27, 2015); *see also* PX7060 (Naclerio (Illumina) IHT at 219-20)).

3696. Dr. Naclerio explained at Illumina had "agreed [that it] would not give another company that same deal, so in other words, such [a] deep discount." (PX7060 (Naclerio (Illumina) IHT at 221).

3697. [redacted] (PX2550 (Illumina) at 001, 019 [redacted] (*in camera*)).

3698. Illumina understood that its 2016 supply and commercialization agreement with Grail provided that "Illumina will not launch, invest in, or provide special discounts to competitive business," which thereby gave Grail "Limited Exclusivity in the field of blood based cancer screening[.]" (PX2183 (Illumina) at 004 (Email from N. Naclerio, Illumina, to A. Pierce, Illumina, et al., attaching Python: Board Approval, Dec. 20, 2015)).

(c) Illumina offered Grail Exclusive Discounts Because of Illumina's Equity Interest in Grail and the Royalty Payments Grail Owed to Illumina

3699. The 2016 presentation Illumina prepared for investors explained that Illumina is not "enabling our customers to sequence at the lower cost that we are giving Grail" because Illumina owned more than "50% of Grail and we get a significant royalty and our customers wouldn't be able to give us those type of economics." (PX2543 (Illumina) at 001 (Illumina, GRAIL FAQs, Jan. 11, 2016); deSouza (Illumina) Tr. 2199).

3700. Mr. deSouza agreed at trial that, due to the royalty payment and Illumina's equity interest in Grail, it made financial sense for Illumina to provide a discount to Grail. (deSouza (Illumina) Tr. 2198-99).

3701. Mr. deSouza agreed at trial that Illumina was compensated for the discount it provided Grail through a combination of the cash Grail paid Illumina for sequencers and consumables, royalty, and equity. (deSouza (Illumina) Tr. 2200).

3702. For Illumina to provide the same level of discount to other customers, those customers would also need to have the same combination of sales to Illumina, royalty paid to Illumina, plus equity paid to Illumina. (PX7107 (deSouza (Illumina) Dep. at 196)).

3703. [redacted] (PX7079 (Flatley (Illumina) Dep. at 134-35) (*in camera*)).

(d) Illumina and Grail Collaborated on Development Projects and Designed Custom, Exclusive Products

3704. When Illumina owned more than 50% of Grail, Illumina and Grail collaborated on project development, assay development, software and data analysis, and supply chain management. (PX2541 (Illumina) at 008 (Interim Review K2-GRAIL, Feb. 2, 2017)).

3705. Illumina collaborated with Grail on "extraction methodology to improve library yields" as well as collaborated with Grail on the development of library prep and sequencing kits. Some of these kits were "built specifically for GRAIL." (PX2541 (Illumina) at 010, 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

3706. Illumina created reagent kits "[p]urpose built for GRAIL" to accommodate Grail's high throughput ctDNA sequencing. (PX2541 (Illumina) at 008, 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

3707. An Illumina presentation reveals that, after its spinoff, Grail had concerns that it was receiving kits from Illumina "from different lots." (PX2541 (Illumina) at 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

3708. Prior to its spinoff, Grail's [k]its were purpose built specifically for GRAIL to support single lot shipments and ease of qualification into GRAIL laboratory." (PX2541 (Illumina) at 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

b) <u>After Illumina's Sale of Its Majority Interest in Grail, Illumina "Leveled" the Playing Field Between Grail and Its Competitors</u>

(1) Illumina Sold Its Majority Interest in Grail as Part of Grail's Series B Financing

3709. In early 2017, Grail initiated its Series B financing to raise over $1 billion. (deSouza (Illumina) Tr. 2202). During Grail's Series B financing, Illumina made the decision to reduce its ownership interest in Grail. (deSouza (Illumina) Tr. 2202). Post-Series B financing, Illumina's ownership interest in Grail reduced from a majority ownership interest to less than 20% of Grail. (deSouza (Illumina) Tr. 2202).

3710. [redacted] } (PX4291 (Grail) [redacted] (*in camera*).

3711. To effectuate its spinoff of Grail, Illumina "had to give up" its seats on Grail's board of directors; Flatley "had to step out of" the role as Grail's chairman; and Illumina "truly had to kick [Grail] off and treat them under commercial agreements like any other customer[.]" (PX7057 (Flatley (Illumina) IHT at 158–60)).

(a) Illumina Decreased Its Ownership in Grail to Allow Grail to Raise More Capital

3712. At the time when Illumina considered spinning off Grail, Illumina determined that Grail's "technology needed to have a much higher level of investment than we originally thought." (PX7057 (Flatley (Illumina) IHT at 158–60)).

3713. [redacted] } (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 9 (RFA No. 6) (*in camera*)).

(b) Illumina Decreased Its Ownership in Grail to Increase Shareholder Value

3714. According to Jay Flatley "probably [the] single biggest factor in considering de-consolidating" was Illumina's desire to "[a]void significant dilution" of Illumina's earnings. (PX7079 (Flatley (Illumina) Dep. at 146–47)).

3715. During "the time when [Flatley] was chairman … half the loss of GRAIL was debited to [Illumina's] income statement, so … we were diluting our income statement." (PX7057 (Flatley (Illumina) IHT at 158–60)).

3716. When Illumina had a majority stake in Grail, "Illumina had to consolidate the losses of GRAIL in proportion to [Illumina's] ownership." (PX7057 (Flatley (Illumina) IHT at 158–60)).

3717. While deSouza testified that multiple reasons factored into Illumina's decision to reduce its ownership percentage in Grail; he agreed with Jay Flatley that one reason was that Illumina felt that it created more shareholder value for Illumina to lower its stake in Grail and, as custodians of shareholder money, Illumina needed to assess what was going to drive returns for shareholders. (deSouza (Illumina) Tr. 2202-03).

3718. [redacted] } (PX2862 (Illumina) at 005 (Email from M. Stapley, Illumina, to J. Flatley, Illumina, F. deSouza, Illumina, P. Scagnetti, Illumina, D. Moriarty, Illumina, R. Chambers, Illumina, M. Bouchard, Illumina, S. Davies,

Illumina, C. Dadswell, Illumina, W. Valencia, Illumina, Dec. 7, 2016, attaching "Grail Series B Overview," Dec. 7, 2016) (*in camera*)).

3719. When Flatley and other Illumina leaders "realized how much [Illumina was] going to have to spend and [Illumina] took a look at how much more dilution that was going to cause Illumina, [Illumina] decided that was untenable" because Illumina's "shareholders would not tolerate that level of dilution[.]" (PX7057 (Flatley (Illumina) IHT at 158–60)).

3720. A "benefit for Illumina" that resulted from spinning off Grail was "avoiding the significant dilution [Illumina] otherwise incur[s] based on GRAIL's necessary expenditures." (PX7079 (Flatley (Illumina) Dep. at 147)).

3721. Another one of the financial benefits of spinning off Grail was a "[o]ne-time $500 million cash inflow" to Illumina "from the sale of [Illumina's] equity [position]" in Grail. (PX7079 (Flatley (Illumina) Dep. at 147–48)).

(c) Illumina Decreased Its Ownership Percentage in Grail to Allow It to Operate More Nimbly and ATTRACT TALENT

3722. [redacted] } (PX7066 (Freidin (Grail) IHT at 21) (*in camera*)).

3723. Nick Naclerio also explained that as an independent company Grail was "able to raise money and attract people in way that would be difficult for Illumina, at the time, you know, to have done." (PX7089 (Naclerio (Illumina) Dep. at 254)). Naclerio also said that operating as an independent company would allow it to attract "high-price talent" and investment as well be more "nimble." (PX7089 (Naclerio (Illumina) Dep. at 252-53)).

(d) Illumina Decreased Its Ownership Percentage in Grail to "Level the Playing Field" for Tts Other Customers Developing Early Cancer Detection Tests

3724. At the time of the Series B financing, other companies were beginning to get interested in developing liquid biopsy tests. (deSouza (Illumina) Tr. 2202).

3725. At the time of the Series B, companies were trying different approaches to do early cancer detection. (deSouza (Illumina) Tr. 2203).

3726. Mr. deSouza was responsible for attending investor calls. (PX7107 (deSouza (Illumina) Dep. at 246)).

3727. During calls with investors, it is important to be truthful and accurate. (PX7107 (deSouza (Illumina) Dep. at 246)).

3728. In fact there are "laws you might break" if you are not and there may also be a "reputational impact." (PX7107 (deSouza (Illumina) Dep. at 246)).

3729. Illumina ordinary course documents from this period also corroborate the rationale that Illumina executives provided for decreasing its ownership percentage of Grail. Notably, Illumina explained that it was going to operate Grail at "Arms length" and that it wanted "Grail to fuel a technology arms race in liquid biopsy" and expected "[m]any other customers may pursue the same opportunity." (PX2624 (Illumina) at 009 (Email from D. Moriarty, Illumina, to J. Benson, Illumina, D. Baker, Illumina, Jan. 11, 2017, attaching "Grail Series B Overview," Jan. 5, 2017)).

3730. Mr. deSouza testified that, when Illumina sold its shares in Grail in 2017, Illumina "didn't want to be tied to just one approach":

> "[W]e wanted to see which approach would work so that we could figure out in the end what was the right way to go, because it wasn't clear to anybody in the market which way to go, and we didn't want to be tied to just one approach. So it gave us the opportunity to assess which way the market was going to go and which technology would work."

(deSouza (Illumina) Tr. 2204).

3731. Jay Flatley – CEO of Illumina at the time – corroborated Mr. deSouza's testimony and explained that Illumina did not want to enter a new market through its subsidiary because "then customers wouldn't want to participate in those markets because they'd believe that Illumina would always underprice them if [it] wanted to." As such, if Grail wanted to enter into a new market "they'd have to do it on a level play field with the existing customers in the market. We thought that was fair to [Grail] and fair to our existing customers." (PX7057 (Flatley (Illumina) IHT at 167-168)).

(2) After Illumina Relinquished Its Majority Ownership It Operated at Arms-Length to Grail

3732. Illumina understood that [redacted] (PX2862 (Illumina) at 005 (Email from M. Stapley, Illumina, to J. Flatley, Illumina, F. deSouza, Illumina, P. Scagnetti, Illumina, D. Moriarty, Illumina, R. Chambers, Illumina, M. Bouchard, Illumina, S. Davies, Illumina, C. Dadswell, Illumina, W. Valencia, Illumina, Dec. 7, 2016, attaching "Grail Series B Overview," Dec. 7, 2016) (*in camera*)).

3733. Illumina understood that the [redacted]. (PX2862 (Illumina) at 005 (Email from M. Stapley, Illumina, to J. Flatley, Illumina, F. deSouza, Illumina, P. Scagnetti, Illumina, D. Moriarty, Illumina, R. Chambers, Illumina, M. Bouchard, Illumina, S. Davies, Illumina, C. Dadswell, Illumina,

W. Valencia, Illumina, Dec. 7, 2016, attaching "Grail Series B Overview," Dec. 7, 2016) (*in camera*)).

3734. Illumina decided not to "have a board seat on Grail" because "[t]o avoid accounting for GRAIL's losses as an equity method investment, it required them to be truly independent." (PX2406 (Illumina) at 005 (Email from J. Flatley, Illumina, to E. Endicott, Illumina, M.c Stapley, Illumina, F. deSouza, Illumina, R. Chambers, Illumina, D. Moriarty, Illumina, S. Davies, Illumina, P. Scagnetti, Illumina, M. Bouchard, Illumina, L. Zinser, Illumina, Jan. 2, 2017)).

(3) After Illumina Sold Its Majority Interest in Grail, Illumina Took Steps to Achieve Parity between Grail and Illumina's Other Customers

3735. At the time of Grail's Series B financing, Jay Flatley, Executive Chairman of Illumina, had executive responsibility for the Series B financing. (deSouza (Illumina) Tr. 2209). In edits to a draft Q&A to investors, Mr. Flatley wrote in response to the question "[b]y creating and unleashing Grail have you created a competitor for your customers?" that the Series B financing "actually leveled the playing field" because "[p]reviously Grail had access to technology and pricing that was preferential to our customers, albeit just for the asymptomatic screening market. Today, GRAIL has access to technology on same terms and price as other large customers, and is funding to perform large scale studies." (PX2406 (Illumina) at 005 (Email from J. Flatley, Illumina, to E. Endicott, Illumina, M. Stapley, Illumina, F. deSouza, Illumina, R. Chambers, Illumina, D. Moriarty, Illumina, S. Davies, Illumina, P. Scagnetti, Illumina, M. Bouchard, Illumina, L. Zinser, Illumina, Jan. 2, 2017); (deSouza (Illumina) Tr. 2210-11)).

3736. Jay Flatley's testimony also corroborates his ordinary course documents. He testified that "what [Illumina] did not want to do was essentially provide a very high discount rate to an entity that was inside of Illumina that would then go compete with our existing customers. And so, you know, if they were going to do that, they would have to do it at market pricing." (PX7057 (Flatley (Illumina) IHT at 165)).

3737. Flatley explained that Illumina's sale of Grail's shares in 2017 made Grail "an arm's length entity to Illumina," which meant that Illumina "would treat [Grail] like [Illumina] would any other customer at that point in time." (PX7079 (Flatley (Illumina) Dep. at 148–49)).

3738. As a result, the deeper discounts Illumina provided to Grail "went away" after the Series B financing. (deSouza (Illumina) Tr. 2207).

3739. [redacted] (PX2862 (Illumina) at 007 (Email from M. Stapley, Illumina, to J. Flatley, Illumina, F. deSouza, Illumina, P. Scagnetti, Illumina, D. Moriarty, Illumina, R. Chambers, Illumina, M. Bouchard, Illumina, S. Davies, Illumina, C. Dadswell, Illumina, W. Valencia, Illumina, Dec. 7, 2016, attaching "Grail Series B Overview," Dec. 7, 2016) (*in camera*)).

3740. As former CEO, Jay Flatley testified at his deposition, after the Series B financing, Illumina was "not involved with GRAIL at an operation level" and did not "have a strategic agreement about any operational work[.]" (PX7079 (Flatley (Illumina) Dep. at 49)).

3741. [redacted]

[redacted]

{ }

(PX2541 (Illumina) at 008 (Interim Review K2-GRAIL, Feb. 2, 2017) (*in camera*)); *see also* PX6090 (Scott Morton Report) ¶ 208 (*in camera*); PX2712 (Illumina) at 042 (Email from P. Scagnetti, Illumina, to M. Nguyen, Illumina, Dec. 3, 2019, attaching "Python Update," Dec. 12, 2015) (explaining that Illumina was helping with "Joint development and IP" prior to the spin off)).

3742. After Grail's Series B fundraising, when Illumina reduced its Grail ownership stake below 50 percent, Illumina and Grail no longer collaborated on development of library prep and sequencing kits. (deSouza (Illumina) Tr. 2456).

c) <u>After Illumina "Leveled the Playing Field," Other Illumina Customers Successfully Developed Asymptomatic Cancer Tests</u>

3743. As Jay Flatly explained in his draft Q&A statements to investors, Illumina expected that its decision to grant Grail "access to technology on same terms and price as other large customers … will accelerate the liquid biopsy market for all." PX2406 (Illumina) at 005 (Email from J. Flatley, Illumina, to E. Endicott, Illumina, M. Stapley, Illumina, F. deSouza, Illumina, R. Chambers, Illumina, D. Moriarty, Illumina, S. Davies, Illumina, P. Scagnetti,

Illumina, M. Bouchard, Illumina, L. Zinser, Illumina, Jan. 2, 2017); deSouza (Illumina) Tr. 2211)).

3744. Since Grail's Series B financing, the number of companies developing liquid biopsy tests has increased. (*See* deSouza (Illumina) Tr. 2212-15; PX2544 (Illumina) at 019 (Email from T. Peterson, JPMorgan, to F. deSouza, Illumina, Sept. 5, 2019, attaching JPMorgan, "Transcript of JPM Life Sciences CEO Conference Call," Sept. 3, 2019)).

3745. In a September 3, 2019 investor conference call that was part of a JPM Life Sciences CEO conference call series, Mr. deSouza told investors: "In liquid biopsy [Illumina was] one of the catalysts of that space as a whole when we incubated Grail internally and then spun it out. We're continuing to work and I think now we're tracking over 70 companies that are doing liquid biopsy in some form or another." (PX2544 (Illumina) at 019 (Email from T. Peterson, JPMorgan, to F. deSouza, Illumina, Sept. 5, 2019, attaching JPMorgan, "Transcript of JPM Life Sciences CEO Conference Call," Sept. 3, 2019)).

3746. In the period after the Series B financing, Illumina supported companies developing liquid biopsy tests. (*See* deSouza (Illumina) Tr. 2214; PX2544 (Illumina) at 019 (Email from T. Peterson, JPMorgan, to F. deSouza, Illumina, Sept. 5, 2019, attaching JPMorgan, "Transcript of JPM Life Sciences CEO Conference Call," Sept. 3, 2019)).

3747. In the September 3, 2019 JPM Life Sciences CEO conference call, Mr. deSouza stated that, of the 70 companies that are doing liquid biopsy, "[w]e continue to support them in some cases, it's making sure that they have access to the best of our workflow even on the front end or on the back end. In some cases it's planning with them what their path to a regulated offering could be, cleared offering. And so we're continuing to work with them in a number of different ways to enhance their ability to expand their market, because, what's good for them is obviously good for us too." (PX2544 (Illumina) at 019 (Email from T. Peterson, JPMorgan, to F. deSouza, Illumina, Sept. 5, 2019, attaching JPMorgan, "Transcript of JPM Life Sciences CEO Conference Call," Sept. 3, 2019)).

3748. Indeed, since the time of the Series B financing, MCED developers have invested in MCED testing and are now poised to commercialize a successful MCED test. (*See supra* Section VI. (Competitors Are Racing to Develop MCED Tests)).

2. Illumina Identified and Used Similar Tools in the Oncology Therapy Selection Market

3749. As Illumina's SVP and General Manager of the Americas business unit, Mr. Daly was responsible for overseeing all commercial operations, including sales, marketing, customer service, and field service support. (PX7109 (Daly (Singular Genomics) Dep. at 15)).

3750. When testifying regarding [redacted]

[redacted]

(PX7109 (Daly (Singular Genomics) Dep. at 93) (*in camera*)).

3751. When asked whether [redacted]

(PX7109 (Daly (Singular Genomics) Dep. at 94) (*in camera*)).

a) Illumina Withheld Agreements to Prevent Competitors in the Therapy Selection Space from Cannibalizing Illumina's Therapy Selection Product

(1) Therapy Selection Tests Use an Array of Datapoints to Help Determine the Best Treatment for a Patient's Cancer

3752. A therapy selection test is a test "looking at the DNA [or some other analyte] of a patient out of tissue or blood, using Next-Generation Sequencing technology to… produc[e] the data that is giving the oncologist information on whether the patient is more likely to [] respond to one treatment or another." (PX7112 (Bailey (PGDx) Dep. at 16-17)).

3753. [redacted] (PX7118 (Fiedler (FMI) Dep. at 54); (PX7061 (Davy (Illumina) IHT at 153) (*in camera*)).

3754. [redacted] (PX7061 (Davy (Illumina) IHT at 153) (*in camera*)).

(2) Illumina Developed an Oncology Therapy Selection Test That Uses Its NGS platform

3755. Illumina has a therapy selection test called TruSight Oncology or TSO-500. (PX7063 (Berry (Illumina) IHT at 25)).

3756. [redacted] (PX2035 (Illumina) at 017 (Illumina,

Oncology Testing 5-Year Strategy Refresh, 2020) (*in camera*)); Leite (Illumina) Tr. 2074-75); *see* PX0091 at 018 (Illumina Source Book, Aug. 2020)).

3757. The TSO-500 uses Illumina's NGS platform. (Leite (Illumina) Tr. 2076-77).

3758. The TSO-500 test interrogates tumors from patients who are actively being managed for oncology or cancer care where physicians have specific questions as to how to treat the tumors. (Leite (Illumina) Tr. 2074).

3759. The TSO-500 is also capable of indicating tumor mutation burden—a scoring system for determining if a patient is likely to respond to immunotherapies. (Leite (Illumina) Tr. 2078; PX7052 (Leite (Illumina) IHT at 120)).

3760. [redacted] (PX7052 (Leite (Illumina) IHT at 121-22 (*in camera*)).

3761. [redacted]

[redacted]

(PX7052 (Leite (Illumina) IHT at 120-21) (*in camera*); (*See also* Leite (Illumina) Tr. 2079 (Mr. Leite testifying that TMB was a selling point for TSO-500)).

3762. Mr. Leite was Illumina's former Vice President of oncology product marketing and market development. (PX7052 (Leite (Illumina) IHT at 21)).

3763. [redacted] (PX7063 (Berry (Illumina) IHT at 25-26, 27) (*in camera*)).

3764. {[redacted]} (PX7063 (Berry (Illumina) IHT at 27) (*in camera*)); PX7080 (Silvis (Tempus) Dep. at 47) (*in camera*))).

3765. Illumina has created different versions of TSO-500 – a liquid biopsy and tissue version. (Leite (Illumina) Tr. 2077-78).

3766. The "kit content" provided on the TSO500 ctDNA assay "is the same as the TSO500 tissue." (PX2004 (Illumina) at 003 (Email from A. Gutierrez, Illumina, to J. Godsey, Illumina, attaching "TSO500 FAQ slides," July 13, 2020.

3767. Ms. Berry testified that some of Illumina's "customers are seeking to deploy [TSO-500] as a laboratory-developed test." (PX7063 (Berry (Illumina) IHT at 26)).

3768. The TSO-500 test is an IVD test. (Leite (Illumina) Tr. 2076).

3769. The Illumina reagents used for the TSO-500 test are unique reagents designed for the TSO-500 specific use case. (PX7063 (Berry (Illumina) IHT at 33)).

3770. [redacted] } (PX2120 (Illumina) at 019 [redacted] (*in camera*))).

3771. eORB stands for "The Executive Opportunity Review Board" and it's made up of Illumina's CEO, Francis deSouza, and his direct reports. (PX7052 (Leite (Illumina) IHT at 32-34)).

3772. [redacted] } (PX7043 (Gunn (Roche) IHT at 38) (*in camera*); PX7112 (Bailey (PGDx) Dep. at 33, 35); PX7040 (Getty (Guardant) IHT at 99)).

3773. [redacted] (PX7043 (Gunn (Roche) IHT at 54) (*in camera*)); PX7118 (Fiedler (FMI) Dep. at 19-20) (*in camera*)); PX7049 (Bailey (PGDx) IHT at 29)); PX7040 (Getty (Guardant) IHT at 56) (*in camera*)).

(3) [redacted]

3774. [redacted] (PX7052 (Leite (Illumina) IHT at 211) (*in camera*)).

3775. [redacted] } (PX7040 (Getty (Guardant) IHT at 82) (*in camera*)). [redacted]

} (PX7040 (Getty (Guardant) IHT at 82) (*in camera*)).

(a)

3776. (PX2123 (Illumina) at 002 (Email from G. Hampton, Illumina, to J. Leite et al., Illumina, attaching slides, Dec. 5, 2018 (*in camera*)).

3777. (PX2123 (Illumina) at 007 (Email from G. Hampton, Illumina, to J. Leite et al., Illumina, attaching slides, Dec. 5, 2018 (*in camera*)).

3778. } (PX7052 (Leite (Illumina) IHT at 167-68) (*in camera*)).

3779. (PX2123 (Illumina) at 004 (Email from G. Hampton, Illumina, to J. Leite et al., Illumina, attaching slides, Dec. 5, 2018 (*in camera*)).

3780. (PX7052 (Leite (Illumina) IHT at 184) (*in camera*));
(PX2095 (Illumina) at 004 (*in camera*)).

3781. (PX7112 (Bailey (PGDx) Dep. at 89) (*in camera*)).

3782. [redacted] (PX7112 (Bailey (PGDx) Dep. at 89) (*in camera*)).

(4) An IVD Agreement is a De Facto Requirement to Create a Kitted Decentralized Test

3783. [redacted] } (PX7052 (Leite (Illumina) IHT at 52) (*in camera*)).

3784. [redacted] (PX7052 (Leite (Illumina) IHT at 53-54) (*in camera*)).

3785. [redacted] } (PX7049 (Bailey (PGDx) IHT at 43) (*in camera*)). [redacted] } (PX8351 (Roche) at 003 [redacted] (*in camera*)); PX7068 (Perettie (FMI-Roche) IHT at 81) (*in camera*)).

3786. Ms. Bailey, PGDx's CEO, testified that PGDx needed an IVD agreement from Illumina to "initiate the development plans, study plans and process to submit a product to the FDA." (PX7112 (Bailey (PGDx) Dep. at 37)).

3787. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 81-82) (*in camera*)).

3788. [redacted] (PX7049 (Bailey (PGDx) IHT at 42-43) (*in camera*)).

3789. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 82) (*in camera*)).

3790. Mr. Leite testified that "IVD Agreements"—co-development agreements or collaboration agreements where Illumina would provide access to its NGS platform so that the IVD test provider could validate its assays on Illumina's instruments, secure quality agreements with Illumina, and secure supply agreements with Illumina that would supply the IVD provider during their development period. (Leite (Illumina) Tr. 2081).

3791. The IVD Agreements that Dr. Leite negotiated also included provisions related to "a quality agreement, as well as an Illumina development of a software module to include the partner's assay manifest, as well as reporting capability into [Illumina's] instrument." (Leite (Illumina) Tr. 2082).

3792. According to Dr. Leite, an IVD Agreement provision related to Illumina's software module was necessary because:

> IVD platforms are by definition what's called a locked box. So to preserve the integrity of the data flow and the audit trail, nothing about the instruments may be changed by the user to ensure the integrity of the clinical data being generated.
>
> So a partner would contract with Illumina to have their assay included as part of that software system and have the report be reported out. This is common practice in the industry.

(Leite (Illumina) Tr. 2082-83).

3793. IVD platforms are a locked box due to FDA requirements related to maintaining data integrity and the ability to audit results on the platform. (Leite (Illumina) Tr. 2082-83).

3794. [redacted] (PX7049 (Bailey (PGDx) IHT at 102) (*in camera*)).

3795. [redacted] (PX7049 (Bailey (PGDx) IHT at 102-03) (*in camera*)).

3796. Ms. Bailey testified that inquiries regarding the existence an IVD agreement with Illumina was a "standard request by the agency to see that were was in fact that direct relationship between manufacture of platform and manufacture of content, and so not having that [agreement] required [PGDx] to find and collaborate with the FDA on a different path to be able to demonstrate to them that we could in fact control for quality end to end without having that agreement in place." (PX7049 (Bailey (PGDx) IHT at 98)).

3797. [redacted] (PX7049 (Bailey (PGDx) IHT at 42-43) (*in camera*)).

3798. [redacted] (PX7040 (Getty (Guardant) IHT at 90-91) (*in camera*)).

3799. [redacted] (PX7040 (Getty (Guardant) IHT at 92) (*in camera*) ([redacted])).

(5) Illumina Only Wanted to Allow "Partnerships" with Companies Who Are Complementary and Not Competitive

3800. In negotiating IVD agreements, Dr. Leite and his colleagues considered whether a customer's oncology therapy selection tests would compete with the TSO-500. (Leite (Illumina) Tr. 2083-84).

3801. [redacted] (PX2102 (Illumina) at 004 [redacted] (*in camera*)).

3802. [redacted] (PX2102 (Illumina) at 004 [redacted] Feb. 4, 2019 (*in camera*) (see image inset)).

[redacted]

{ }

3803. [redacted] } (PX2677 (Illumina) at 001 (Email from D. Daly, Illumina, to N. Berry, Illumina, Feb. 6, 2019 (*in camera*) ({[redacted]))).

3804. [redacted] } (PX2203 (Illumina) at 001 (Email from J. Leite, Illumina, to J. Mayew, J. Eidel, Illumina, Apr. 4, 2018) (*in camera*)).

3805. As part of Illumina's strategy, Dr. Leite and his colleagues considered competitive factors in determining Illumina's negotiation strategy, such as:

> [T]he value of inclusion of partners that were developing solutions close to ours. We considered a term called "cannibalization" -- in other words, what would be the sales of Illumina TSO-500 in the absence of these partners versus the presence of these partners—to try and decide at least a framework for summing up what the value of that partnership should be.

(Leite (Illumina) Tr. 2085).

3806. Dr. Leite testified that Illumina took into account the net loss in TSO-500 sales that might result from a partnership with a customer:

> And so we certainly wanted to quantify from a financial loss perspective what would be the worst case scenario, and we knew that that had to be our floor and that anything that we could gain from a partnership consideration in terms of up-front payments or total deal value should at least look to mitigate some of that risk.

(Leite (Illumina) Tr. 2087).

3807. In negotiating IVD agreements, Dr. Leite testified that Illumina dictates which tests gain an IVD agreement and accept customer proposals only if they made financial sense for Illumina. (Leite (Illumina) Tr. 2187).

3808. When negotiating with oncology therapy selection test developers, Dr. Leite testified at trial that "the ability to maximize penetration into the oncology market was always a consideration. As part of our strategy, we considered the value of inclusion of partners that were developing solutions close to ours. We considered a term called 'cannibalization' – in other words, what would be the sales of Illumina TSO-500 in the absence of these partners versus the presence of these partners – to try and decide at least a framework for summing up what the value of that partnership should be." (Leite (Illumina) Tr. 2084-85).

b) [redacted]

(1) [redacted]

3809. [redacted] } (RX0485 (Roche) at 060 [redacted] (*in camera*)); Leite (Illumina) Tr. 2105-06 (*in camera*)).

3810. [redacted] } (RX0485 (Roche) at 060 [redacted] (*in camera*)).

3811. [redacted] (RX0485 (Roche) at 060 [redacted] (*in camera*)).

3812. [redacted] (RX0485 (Roche) at 060 [redacted] (*in camera*)).

(a) The AVENIO Kits

3813. "The AVENIO kits are a packaged solution [] able to run a sequencing assay on the Illumina platform." (PX7043 (Gunn (Roche) IHT at 37)).

3814. [redacted] } (PX7043 (Gunn (Roche) IHT at 37-38) (*in camera*)).

3815. [redacted] } (PX7043 (Gunn (Roche) IHT at 38-39) (*in camera*)).

3816. The AVENIO kits have the regulatory classification of research use only (RUO) which "is an official regulatory classification, [meaning] that [] labs can use them for research purposes, and they have to – there are instructions for use. They are provided as a kit, and they are used in that context." (PX7074 (Gunn (Roche) IHT at 51)).

3817. Because the AVENIO kits are RUO only, for labs to run the AVENIO kits in their own labs they must operate it as a laboratory developed test. Meaning, they have to validate it within their own workflow, and they have to validate the results that come off it." (PX7074 (Gunn (Roche) IHT at 51)).

3818. [redacted] } (PX7074 (Gunn (Roche) IHT at 53-54) (*in camera*)).

(b) FoundationOne Assays

3819. FoundationOne is a tissue-based therapy selection test. (PX7068 (Perettie (FMI-Roche) IHT at 25)).

3820. The FoundationOne test was launched in 2012. FoundationOne CDx is the FDA-approved test companion diagnostic version of FoundationOne. (PX7068 (Perettie (FMI-Roche) IHT at 24-25)).

3821. The FoundationOne CDx test is a "tissue-based test that [] looks for 324 genes that are associated with cancer… [FMI is] able to inform the oncologist or the biopharma partner and the patient which genes [the test has] found in their individual cancer. And that enables a treatment decision." (PX7068 (Perettie (FMI-Roche) IHT at 25)).

3822. The FoundationOne test can measure tumor mutational burden or TMB. (PX7068 (Perettie (FMI-Roche) IHT at 27)).

3823. TMB is "a number of genes that form a biomarker that are indicative of patients that would respond to cancer immunotherapy." (PX7068 (Perettie (FMI-Roche) IHT at 27)).

3824. FMI had the ability to measure TMB from a research and development standpoint since 2017, but it was not until 2019 that it was officially FDA approved. (PX7068 (Perettie (FMI-Roche) IHT at 27)).

3825. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 28 (*in camera*))). [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 28 (*in camera*))).

3826. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 32) (*in camera*)).

3827. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 32 (*in camera*))).

3828. When FoundationOne was initially launched it was launched as a laboratory developed test or "LDT." (PX7068 (Perettie (FMI-Roche) IHT at 34)).

3829. "A laboratory developed test is a test that passes a CLIA certification or New York certification… It is a test that can be used in clinical practice, but [] it [has] a slightly – a lower bar than going through an FDA process." (PX7068 (Perettie (FMI-Roche) IHT at 34-35)).

3830. "LDTs can be used to guide treatment decision in the clinic." "[W]ith an LDT, there's a certain number of things you do to add or subtract genes… that require some validation not at the same rigor [as] FDA [approval]." (PX7068 (Perettie (FMI-Roche) IHT at 35)).

3831. Today, the FoundationOne test is an in vitro diagnostic test. (PX7068 (Perettie (FMI-Roche) IHT at 35)).

3832. An in vitro diagnostic or IVD is "a test that has passed that rigor to have an FDA approval and used to guide treating physicians and patients." (PX7068 (Perettie (FMI-Roche) IHT at 36)).

3833. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 33 (*in camera*))).

3834. IVDs and LDTs are governed differently. "[F]or an LDT, you have the ability to make more rapid changes to it. It doesn't go through a process of intense review with the FDA. Instead, it's a much lighter process to make changes than you would with an IVD." (PX7068 (Perettie (FMI-Roche) IHT at 36)).

(2) [redacted]}

3835. The AVENIO test kits require an NGS platform to be used. (PX7043 (Gunn (Roche) IHT at 54)). Specifically, "the AVENIO kits and all kits actually have to be designed with the platform in mind, and so Roche developed the AVENIO kits with the direct purpose of running them on the Illumina NextSeq instrument." (PX7043 (Gunn (Roche) IHT at 54)).

3836. [redacted]} (RX0485 (Roche) at 060 [redacted] (*in camera*))).

3837. "Comprehensive genomic profiling tests are tests that look at a wide range of mutations of tumor tissue to understand, connect what genomic mutations happens to the tumor to decide on a treatment plan. And the word 'comprehensive' is because it's not just one mutation that is checked, but it's a wide range of mutations." (PX7118 (Fiedler (FMI) Dep. at 18)).

3838. Mr. Fielder testified that Illumina's products are essential to FMI's comprehensive genomic profiling tests "because the design of the test is based on the Illumina technology. The Illumina technology has one central element. It is called 'hybrid capturing' where you connect, prepare the gene in the way that you can selectively look at mutations, and that is a unique offering at this stage for Illumina." (PX7118 (Fiedler (FMI) Dep. at 19)).

3839. [redacted] (PX7118 (Fiedler (FMI) Dep. at 19-20 (*in camera*))).

3840. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 23) (*in camera*)).

3841. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 90) (*in camera*)).

3842. [redacted] (*See* PX7068 (Perettie (FMI-Roche) IHT at 90-91) (*in camera*) ([redacted])).

(3) [redacted]

3843. [redacted] (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, et al., Dec. 5, 2018) (*in camera*); Leite (Illumina) Tr. 2105-06 (*in camera*)).

3844. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 80-81) (*in camera*)).

3845. [redacted] (PX8351 (Roche) at 011 [redacted] (*in camera*))).

3846. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 81) (*in camera*)).

(4) [redacted]

3847. [redacted] (PX7043 (Gunn (Roche) IHT at 38) (*in camera*) ([redacted]

[redacted]})).

3848. [redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 38 (*in camera*))). {[redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 39 (*in camera*))).

3849. [redacted]

[redacted]}

(PX7068 (Perettie (FMI-Roche) IHT at 38-39 (*in camera*))).

3850. [redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 39 (*in camera*))).

(5) [redacted]}

3851. [redacted]} (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, et al., attaching slides, Dec. 5, 2018) (*in camera*); *see* PX2089 (Illumina) (Email from T. Dodge, Illumina, to D. Daly, Illumina, et al., Aug. 31, 2018) (*in camera*); Leite (Illumina) Tr. 2105-06 (*in camera*); PX7061 (Davy (Illumina) IHT at 153) (*in camera*)).

3852. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 81) (*in camera*)).

3853. [redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 17-18, 80-81) (*in camera*)).

3854. { [redacted] (PX7061 (Davy (Illumina) IHT at 154) (*in camera*)).

3855. [redacted] } (Leite (Illumina) Tr. 2102 (*in camera*)). { [redacted] } (Leite (Illumina) Tr. 2102 (*in camera*); *see* PX2095 (Illumina) at 001 (Email from J. Leite, Illumina, to G. Hampton, Illumina, et al., attaching slides, Dec. 5, 2018) (*in camera*)).

3856. [redacted] } (*See* PX2119 (Illumina) at 002-003 (Email from K. Davy, Illumina, to G. Hampton, Illumina, attaching slides, Feb. 12, 2018) (*in camera*) ({ [redacted] }); PX7052 (Leite (Illumina) IHT at 26-27) (*in camera*) ({ [redacted] }); PX2117 (Illumina) [redacted] (*in camera*)).

3857. [redacted] } (PX2123 (Illumina) at 003 (Email from K. Davy, Illumina, to K. Keegan, Illumina, attaching slides, Dec. 9, 2018) (*in camera*)).

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(PX2123 (Illumina) at 003 (Email from K. Davy, Illumina, to K. Keegan, Illumina, attaching slides, Dec. 9, 2018) (*in camera*); *see* PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, et al., attaching slides, Dec. 5, 2018) (*in camera*) ( ).

3858. (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, et al., attaching slides, Dec. 5, 2018) (*in camera*)).

3859.

[redacted]} (PX7052 (Leite (Illumina) IHT at 170-71) (*in camera*)).

3860. [redacted]} (PX2120 (Illumina) at 004, 006 [redacted] (*in camera*); *see* PX7052 (Leite (Illumina) IHT at 119) ("IO" refers to immuno-oncology, within the field of immunotherapy.)).

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[redacted]

}

(PX2120 (Illumina) at 006 [redacted] (*in camera*)).

3861. [redacted]}

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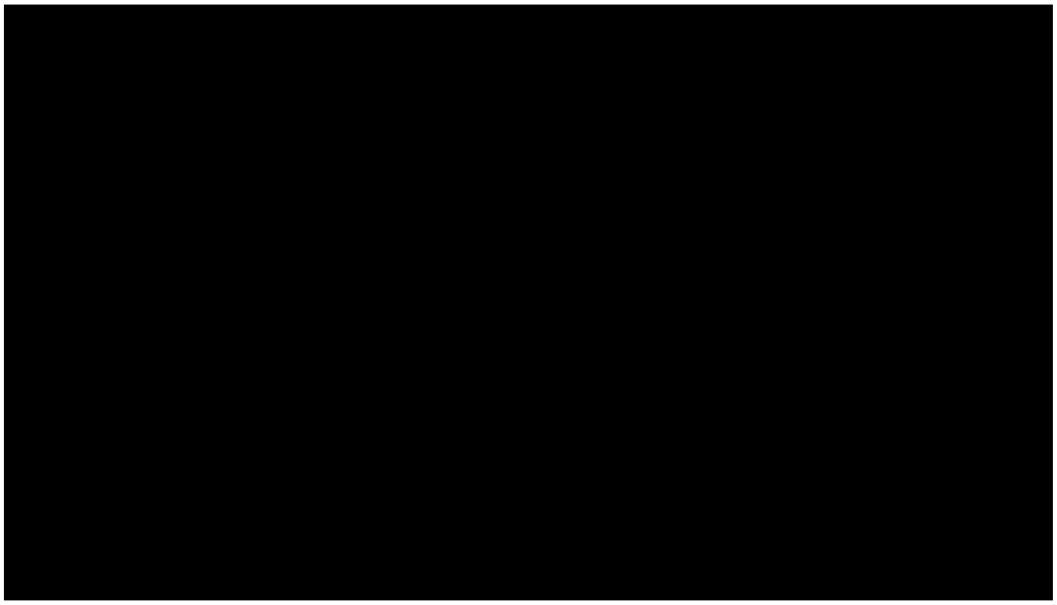

}

(PX2119 (Illumina) at 003 (Email from K. Davy, Illumina, to G. Hampton, Illumina, attaching slides, Feb. 12, 2018) (*in camera*)).

3862. } (PX2120 (Illumina) at 006 (*in camera*)).

3863. (PX2120 (Illumina) at 010 (*in camera*)).

3864.

[redacted]

{ }

(PX2120 (Illumina) at 009 [redacted] (*in camera*)).

3865. [redacted] } (PX2120 (Illumina) at 004 [redacted] (*in camera*)).

[redacted]

{ }

3866. [redacted] (PX2120 (Illumina) at 004 [redacted] (*in camera*)).

3867. [redacted] (PX2120 (Illumina) at 004 [redacted] (*in camera*)).

3868. [redacted] (PX2120 (Illumina) at 007 [redacted] (*in camera*)).

3869. [redacted] (PX2120 (Illumina) at 007 [redacted] (*in camera*))).

3870. [redacted] (PX2095 (Illumina) at 002 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)). [redacted] (PX7052 (Leite (Illumina) IHT at 161-62) (*in camera*); *see* Leite (Illumina) Tr. 2104-05, 2107 (*in camera*)).

3871. [redacted] (PX2123 (Illumina) at 006 (Email from K. Davy, Illumina, to K. Keegan, Illumina, attaching slides, Dec. 9, 2018) (*in camera*)).

3872. [redacted]

[redacted] (PX2122 (Illumina) at 003 (Email from G. Hampton, Illumina, to J. Leite, Illumina, et al., attaching slides, Dec. 5, 2018) (*in camera*) (*see* image inset)).

[redacted]

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3873. [redacted] } (PX2123 (Illumina) at 008 (Email from K. Davy, Illumina, to K. Keegan, Illumina, attaching slides, Dec. 9, 2018) (*in camera*)).

3874. [redacted] (PX2095 (Illumina) at 001 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)).

3875. [redacted]

(PX7052 (Leite (Illumina) IHT at 159-60) (*in camera*)).

3876. } (PX7052 (Leite (Illumina) IHT at 165) (*in camera*)). { } (PX7052 (Leite (Illumina) IHT at 165-66) (*in camera*)).

3877. (PX7052 (Leite (Illumina) IHT at 167) (*in camera*) ({ })).

3878. } (PX7052 (Leite (Illumina) IHT at 174-75) (*in camera*); *see* PX2095 (Illumina) at 004 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)). { (PX7052 (Leite (Illumina) IHT at 175) (*in camera*)).

3879. } (PX7052 (Leite (Illumina) IHT at 176) (*in camera*); *see* PX2095 (Illumina) at 006 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)).

3880. (PX7052 (Leite (Illumina) IHT at 179-80) (*in camera*); *see* PX2095 (Illumina) at 008 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)).

3881. [redacted] (Leite (Illumina) Tr. 2107-08 (*in camera*)).

3882. [redacted] } (PX7052 (Leite (Illumina) IHT at 180-81) (*in camera*)).

3883. [redacted] (PX2095 (Illumina) at 008 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in camera*)).

[redacted]

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(PX2123 (Illumina) at 008 (Email from K. Davy, Illumina, to K. Keegan, Illumina, attaching slides, Dec. 9, 2018) (*in camera*)).

3884. [redacted] } (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, et al., Dec. 5, 2018) (*in camera*); Leite (Illumina) Tr. 2106-07 (*in camera*)).

3885. [redacted] } (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, Illumina, attaching slides, Dec. 5, 2018) (*in*

camera)). {[redacted]} (PX7052 (Leite (Illumina) IHT at 172-73) (*in camera*)).

3886. [redacted] (Leite (Illumina) Tr. 2106-07 (*in camera*)).

3887. {[redacted]} (PX2095 (Illumina) at 003 (Email from J. Leite, Illumina, to G. Hampton, et al., attaching slides, Dec. 5, 2018) (*in camera*); Leite (Illumina) Tr. 2105-07 (*in camera*)).

(a) {[redacted]

3888. [redacted] (PX2199 (Illumina) at 001 (Email from J. Leite, Illumina, to K. Davy, Illumina, et al., July 22, 2019) (*in camera*) ({[redacted]

3889. [redacted] (PX7052 (Leite (Illumina) IHT at 180-81) (*in camera*)).

3890. [redacted] (PX7052 (Leite (Illumina) IHT at 186-87); PX2102 (Illumina) at 001 [redacted] (*in camera*)).

3891. {[redacted]} (PX7052 (Leite (Illumina) IHT at 186) (*in camera*)).

3892. [redacted] } (PX2102 (Illumina) at 004 (*in camera*)). { [redacted] (PX7052 (Leite (Illumina) IHT at 188) (*in camera*)).

3893. [redacted] (PX2102 (Illumina) at 005 (*in camera*)). [redacted] } (PX7052 (Leite (Illumina) IHT at 191) (*in camera*)).

3894. [redacted] (PX2102 (Illumina) at 005 (*in camera*)). [redacted] } (PX2102 at 007-009 [redacted] (*in camera*))).

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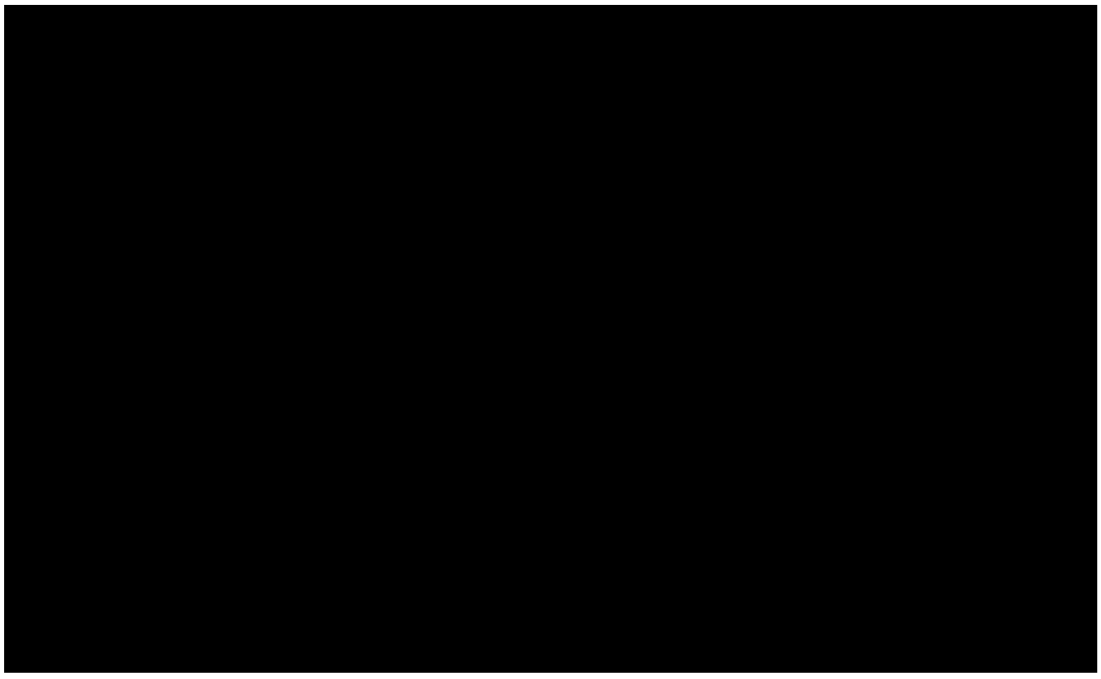
3895. } (*See* PX2124 (Illumina) at 002-003 (*in camera*)).

3896. (PX2125 (Illumina) at 005 (*in camera*); *see* PX2124 (Illumina) at 003 (*in camera*)).

3897. } (PX2124 (Illumina) at 003 (*in camera*))). {

(PX2124 (Illumina) at 003

(*in camera*)); PX2125 (Illumina) at 005 (*in camera*)).



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(PX2125 (Illumina) at 005 (*in camera*)).

3898. { } (Leite (Illumina) Tr. 2110-11 (*in camera*)). { (Leite (Illumina) Tr. 2110-11 (*in camera*)).

3899. } (Leite (Illumina) Tr. 2107-09 (*in camera*)).

3900. (Leite (Illumina) Tr. 2107-09, 2111-12 (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite and K. Davy, Illumina, July 22, 2019) (*in camera*)). (Leite (Illumina) Tr. 2107-09, 2111-12 (*in camera*); PX2199 (Illumina)at 001 (Email from J. Leite, Illumina, to K. Davy, et. al, Illumina, July 22, 2019 (*in camera*)).

[redacted]

(PX2199 (Illumina) at 001 (Email from J. Leite, Illumina, to K. Davy, Illumina, et al., July 22, 2019) (*in camera*)).

3901. [redacted] (PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)).

3902. [redacted] (Leite (Illumina) Tr. 2115 (*in camera*)).

3903. [redacted] (Leite (Illumina) Tr. 2114 (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)).

3904. [redacted] (Leite (Illumina) Tr. 2118 (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)). [redacted]

[redacted] (Leite (Illumina) Tr. 2115 (*in camera*)).

3905. [redacted] (Leite (Illumina) Tr. 2116 (*in camera*)).

3906. [redacted] (*See* Leite (Illumina) Tr. 2120-21 (*in camera*)). [redacted] (Leite (Illumina) Tr. 2120-21 (*in camera*)).

3907. [redacted] (PX2209 (Illumina) (*in camera*); Leite (Illumina) Tr. 2117-19 (*in camera*)). [redacted] (Leite (Illumina) Tr. 2119-20 (*in camera*); PX2209 (Illumina) (*in camera*)).

3908. [redacted] (PX2209 (Illumina) at 017 (*in camera*)).

3909. [redacted] (PX2209 (Illumina) at 017 (*in camera*)).

3910. [redacted] (PX7052 (Leite (Illumina) IHT at 202-04) (*in camera*)); PX2209 (Illumina) at 005 (*in camera*)).

3911. [redacted] (PX7052 (Leite (Illumina) IHT at 203) (*in camera*)).

3912. [redacted] (PX2209 (Illumina) at 005 (*in camera*)).

3913. [redacted] (PX7052 (Leite (Illumina) IHT at 203) (*in camera*)).

3914. [redacted] (PX2209 (Illumina) at 005 (*in camera*)). [redacted] (PX7052 (Leite (Illumina) IHT at 205-06) (*in camera*)).

3915. [redacted] (PX7052 (Leite (Illumina) IHT at 206) (*in camera*)).

3916. [redacted] (PX7052 (Leite (Illumina) IHT at 208) (*in camera*)).

3917. [redacted] (PX2209 (Illumina) at 009 (*in camera*)).

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3918. [redacted] (PX7052 (Leite (Illumina) IHT at 209) (*in camera*)).

3919. [redacted] (PX7052 (Leite (Illumina) IHT at 209) (*in camera*); PX2209 (Illumina) at 009 [redacted] (*in camera*)).

3920. [redacted] (PX2209 (Illumina) at 014 [redacted] (*in camera*)).

3921. [redacted] (PX2209 (Illumina) at 017 [redacted] (*in camera*)).

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3922. (Leite (Illumina) Tr. 2120-21 (*in camera*); PX2209 (Illumina) at 017 (*in camera*)).

3923. (Leite (Illumina) Tr. 2122-24 (*in camera*); PX2209 (Illumina) at 006 (*in camera*)).

} (Leite (Illumina) Tr. 2123 (*in camera*)).

3924. (PX7052 (Leite (Illumina) IHT at 215) (*in camera*)).

3925. (PX7052 (Leite (Illumina) IHT at 213) (*in camera*); PX2209 (Illumina) at 017 (*in camera*)).

3926. (PX7052 (Leite (Illumina) IHT at 213) (*in camera*)).

3927. [redacted] (PX7052 (Leite (Illumina) IHT at 214) (*in camera*)).

3928. [redacted] (PX7052 (Leite (Illumina) IHT at 218) (*in camera*); PX2199 (Illumina) at 001 (Email from K. Davy, Illumina, to K. Keegan, et. al, Illumina, July 22, 2019 (*in camera*)).

3929. [redacted] (PX7052 (Leite (Illumina) IHT at 218-19) (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite, et. al Illumina, July 22, 2019) (*in camera*)).

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[redacted]

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3930. [redacted] (PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)).

3931. [redacted]

[redacted] (PX7052 (Leite (Illumina) IHT at 222-23) (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)).

3932. [redacted] (PX7052 (Leite (Illumina) IHT at 223) (*in camera*); PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina to J. Leite, et. al, Illumina, July 22, 2019) (*in camera*)).

3933. [redacted] } (PX8351 (Roche) (*in camera*)). { } (PX8351 (Roche) at 003 (*in camera*)).

3934. [redacted] (PX8351 (Roche) at 003 (*in camera*)).

3935. { [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 82-83) (*in camera*); PX8351 (Roche) at 003 (*in camera*)).

3936. [redacted] } (PX7068 (Perettie (FMI-Roche) IHT at 83) (*in camera*)).

3937. [redacted] } (PX8351 (Roche) at 012 (*in camera*)).

3938. {[redacted]} (PX8351 (Roche) at 015, 016 [redacted] (*in camera*)).

3939. {[redacted] (Leite (Illumina) Tr. 2126 (*in camera*)). [redacted] (Leite (Illumina) Tr. 2126-27 (*in camera*)).

3940. [redacted] (Leite (Illumina) Tr. 2124-26 (*in camera*)).

(6) [redacted]

3941. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 83) (*in camera*)).

3942. [redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 85) (*in camera*)).

3943. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 39-40, 84) (*in camera*); PX7052 (Leite (Illumina) IHT at 134) (*in camera*)).

3944. {[redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 85) (*in camera*)).

3945. [redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 84-85) (*in camera*)).

3946. [redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 84) (*in camera*)).

3947. [redacted]} (PX8351 (Roche) at 003 [redacted] (*in camera*)).

3948. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 86) (*in camera*) ([redacted])).

3949. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 85) (*in camera*)).

3950. [redacted] (PX7052 (Leite (Illumina) IHT at 201) (*in camera*)).

3951. [redacted] (PX7052 (Leite (Illumina) IHT at 201-02) (*in camera*) ([redacted]))

3952. [redacted] (PX2290 (Illumina) at 005-006 [redacted] (*in camera*); PX2625 (Illumina) at 003, 087 [redacted] (*in camera*)).

3953. The standardized IVD partnership agreement in the Open Offer requires, for IVD rights to all platforms, a tech access fee of $25 million, development milestone payments of $1 million to $5 million per IVD test kit, and a revenue sharing royalty of 6 percent. (PX0087 at 021, 041 (Illumina IVD Test Kit Agreement – All Platforms, dated Mar. 30, 2021)).

(a) {[redacted]}

3954. {[redacted]} (PX8351 (Roche) at 006 [redacted] (*in camera*)). {[redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 88-89) (*in camera*)).

3955. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 89) (*in camera*)).

3956. [redacted] (PX2507 (Illumina) at 001 (Email from S. Young, Illumina, to T. Zaleski, Illumina, et al., Aug. 20, 2019) (*in camera*)). [redacted] (PX2507 (Illumina) at 001 (Email from S. Young, Illumina, to T. Zaleski, Illumina, et al., Aug. 20, 2019) (*in camera*)).

3957. {[redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 89) (*in camera*)). [redacted] (PX2199 (Illumina) at 001 (Email from K. Keegan, Illumina, to J. Leite and K. Davy, Illumina, July 22, 2019) (*in camera*); Leite (Illumina) Tr. 2116-8).

3958. According to Mr. Leite, Illumina required these up-front payments and other fees because "there was a potential for downside risk that we needed to offset through some financial consideration." (Leite (Illumina) Tr. 2163).

c) {[redacted]}

(1) [redacted]

3959. PGDx has two therapy selection products: Elio Tissue Complete and Elio Plasma Resolve. (PX7049 (Bailey (PGDx) IHT at 28-30)).

3960. Ms. Bailey, PGDx's CEO, testified that what PGDx is trying to solve for is "putting it closer [to the patient] so results can be delivered faster and becomes more standard of care, and ultimately… more patients receive [a therapy selection] test." (PX7049 (Bailey (PGDx) IHT at 25)).

(a) Elio Tissue Complete Test

3961. [redacted] (PX7049 (Bailey (PGDx) IHT at 26); PX7112 (Bailey (PGDx) Dep. at 25-6) (*in camera*)).

3962. [redacted] (PX7049 (Bailey (PGDx) IHT at 141) (*in camera*)).

3963. Elio Tissue Complete is a distributed in vitro diagnostic (IVD) test meaning PGDx's customers can run the test in their own lab. (PX7049 (Bailey (PGDx) IHT at 94)).

3964. PGDx's Elio Tissue Complete test uses Illumina's NextSeq instrument. (PX7049 (Bailey (PGDx) IHT at 29)).

(b) Elio Plasma Resolve Test

3965. PGDx began development of the Elio Plasma Resolve test in 2017. (PX7049 (Bailey (PGDx) IHT at 135-36)).

3966. The Elio Plasma Resolve test "is a 33 gene liquid biopsy kit" and "runs out of a blood sample." The Elio Plasma Resolve test is "intended to be pan-cancer in nature" and "report[s] microsatellite instability which is related to immune-oncology therapies." (PX7049 (Bailey (PGDx) IHT at 28)).

3967. The Elio Plasma Resolve test "works very similarly to [] the elio tissue complete test with the primary exception being that the DNA is extracted out of a blood sample." (PX7049 (Bailey (PGDx) IHT at 134-35)).

3968. Because Elio Plasma Resolve can measure microsatellite instability or "MSI" it can be used to indicate for immuno-oncology therapies. (PX7049 (Bailey (PGDx) IHT at 138)).

3969. Elio Plasma Resolve cannot measure tumor mutation burden or "TMB" because the panel is "not big enough to do that accurately." (PX7049 (Bailey (PGDx) IHT at 138-39)).

3970. PGDx's Elio Plasma Resolve test uses next-generation sequencing to analyze the blood sample. Specifically, the Elio Plasma Resolve test runs on the Illumina NextSeq platform. (PX7049 (Bailey (PGDx) IHT at 32-33, 135)).

3971. Elio Plasma Resolve is not FDA cleared. (PX7112 (Bailey (PGDx) Dep. at 28)).

3972. The Elio Plasma Complete test will not fall under the November 2020 Illumina IVD agreement as "that agreement is restricted to the NextSeq platform." PGDx "would have to negotiate and extension or addendum to encompass [] rights to the NovaSeq platform." (PX7049 (Bailey (PGDx) IHT at 162)).

(2) [redacted]

3973. [redacted] (PX7112 (Bailey (PGDx) Dep. at 21-22) (*in camera*)).

3974. During the development process of Elio Plasma Resolve, PGDx did not look at any next generation sequencers other than Illumina's because Illumina has a "broad install base, quality of reads, and the impact of that on performance of the panel, and because it was always the strategy and plan to take the product through the FDA. There are really only two registered instruments with the FDA, the Illumina instruments – I should say two companies that have registered instruments, Illumina and Thermo." (PX7049 (Bailey (PGDx) IHT at 139-40)).

3975. Ms. Bailey testified that PGDx has not considered Thermo Fisher as its next-generation supplier because of "technical reasons around the need for depth of sequence and quality expectations around Illumina's instrument." (PX7049 (Bailey (PGDx) IHT at 140)).

3976. [redacted] (PX7112 (Bailey (PGDx) Dep. at 22) (*in camera*) ([redacted])).

3977. [redacted]

[redacted] (PX7049 (Bailey (PGDx) IHT at 38) (*in camera*)).

3978. [redacted] (PX7049 (Bailey (PGDx) IHT at 153-54) (*in camera*)).

3979. [redacted] (PX7049 (Bailey (PGDx) IHT at 169) (*in camera*)).

3980. [redacted] (PX7052 (Leite (Illumina) IHT at 151-52) (*in camera*)).

(3) [redacted]

(a) [redacted]

3981. Ms. Bailey testified that Illumina's TSO500 is a competitor of the Elio Tissue Complete test. (PX7112 (Bailey (PGDx) Dep. at 33)).

3982. Ms. Bailey testified that Elio Tissue Complete competes with the TSO500 "on content." "The gene content on the panels is very similar, and both are comprehensive across different classes of variants that have mutations relevant to multiple cancer types." (PX7112 (Bailey (PGDx) Dep. at 34)).

3983. Both Elio Tissue Complete and TSO500 are approximately 500 gene panels. (PX7112 (Bailey (PGDx) Dep. at 34)).

3984. Additionally, Elio Tissue Complete and TSO500 compete on "workflow performance" and "turnaround time." (PX7112 (Bailey (PGDx) Dep. at 35) ("Q. Are there any other features that the Elio Tissue Complete will compete with the TSO500 on? A. I mean, from a laboratory perspective, it competes on things like workflow performance, but I think the more obvious, competitive nature, it's just the clinical content on the panel itself. Q. Do they compete in regards to turnaround time? A. Yes.")).

3985. Elio Tissue Complete and TSO500 compete on the indication of tumor mutation burden (TMB). (PX7112 (Bailey (PGDx) Dep. at 35)).

3986. [redacted] (PX7063 (Berry (Illumina) IHT at 84-85) (*in camera*)).

3987. [redacted] } (PX7063 (Berry (Illumina) IHT at 85) (*in camera*)).

3988. [redacted] } (PX7063 (Berry (Illumina) IHT at 85) (*in camera*)).

3989. Ms. Bailey testified that PGDx's 500-gene liquid biopsy test will be competitive with the TSO500 liquid biopsy. (PX7049 (Bailey (PGDx) IHT at 159)).

3990. PGDx plans to launch its 500-gene liquid biopsy test in Q3 2021. (PX7049 (Bailey (PGDx) IHT at 159-60) ("Q. When will PGDx be launching this plasma resolve test with 500 genes? A. Within the next quarter.")).

(4) [redacted] }

3991. [redacted] } (PX7112 (Bailey (PGDx) Dep. at 72) (*in camera*)). At this time, Mr. Doug Ward was the CEO of PGDx. (PX7112 (Bailey (PGDx) Dep. at 42)).

3992. In 2017, PGDx was asking Illumina for "access to the platform and the parameters around codeveloping [PGDx's] test on [Illumina's] platform in the IVD software mode to be submitted to the FDA." (PX7112 (Bailey (PGDx) Dep. at 42-43)).

3993. Ms. Bailey testified that it was her understanding that in 2017 Illumina was "not willing to enter into [an IVD] agreement." (PX7112 (Bailey (PGDx) Dep. at 43)). Ms. Bailey was made aware of Illumina's reaction "through leadership discussions at the time with Doug [Ward] and Jay [Foust] and [PGDx's] head of regulatory's work to discuss with the FDA alternate approaches." (PX7112 (Bailey (PGDx) Dep. at 43)). More specifically, Ms. Bailey testified that Illumina refused PGDx and IVD agreement "because of the development of the TSO500 test. It would be a competitive test on [Illumina's] platform." (PX7112 (Bailey (PGDx) Dep. at 43); PX7049 (Bailey (PGDx) IHT at 96-97); PX2764 (Illumina) at 001 (Email from J. Leite, Illumina, to M. Kreitzinger, Illumina, et al., Feb. 28, 2018)).

3994. Ms. Bailey testified that Illumina's development of TSO500 impacted PGDx's ability to secure an IVD agreement from Illumina because the TSO500 "product would be developed and launched on the same platform and was quite comparable in content to what [PGDx

was] developing, and it was more a desire not to enable the standard path forward for Elio Tissue Complete through the FDA submission." (PX7112 (Bailey (PGDx) Dep. at 45-46); PX7049 (Bailey (PGDx) IHT at 97-98)).

3995. Ms. Bailey testified that the feedback she heard as to why Illumina refused PGDx and IVD agreement prior to November 2020 was "because of the development of the TSO500 test that would be a competitive test on that platform." In other words, because Illumina had a competitive test to PGDx's Elio Tissue Complete Illumina "didn't want to sign a partnership agreement that would have put in place the more standard co-development agreement that would have been supplied as part of [PGDx's] FDA submission process." (PX7049 (Bailey (PGDx) IHT at 97)).

3996. Illumina initially rejected PGDx's request for IVD rights for PGDx's therapy selection test on the grounds that it would "devalue our competitive position significantly." (PX2764 (Illumina) at 001 (Email from J. Leite, Illumina, to M. Kreitzinger, Illumina, et al., Feb. 28, 2018); PX7049 (Bailey (PGDx) IHT at 96-97) (testifying that PGDx believed Illumina did not initially provide PGDx with IVD rights because Illumina's "TSO500 test that would be a competitive test on that platform")).

3997. [redacted] (PX2764 (Illumina) at 001 (Email from J. Leite, Illumina, to M. Kreitzinger, Illumina, et al., Feb. 28, 2018); Leite (Illumina) Tr. 2093-94 (*in camera*)).

3998. PGDx did not enter into an IVD agreement with Illumina in 2017. (PX7112 (Bailey (PGDx) Dep. at 44)).

3999. When Illumina refused to provide PGDx an IVD agreement in 2017 PGDx had "discussions with the FDA, [which] were motivated based on patient care needs in the market, and [] a desire to regulate some of the lab-developed tests of this kind in the market to enable a path forward. But because [PGDx] didn't have some of the standard things in place like the IVD agreement, it required multiple [] pre-sub meetings and discussions to align on an alternate path" to FDA clearance. (PX7112 (Bailey (PGDx) Dep. at 46-47)).

4000. [redacted] (PX2078 (Illumina) at 001 (Email from N. Berry, Illumina, to M. Van Oene, Illumina, Feb. 28, 2018) (*in camera*)). [redacted] (PX2078 (Illumina) at 001 (Email from M. Van Oene, Illumina, to N. Berry, Illumina, Feb. 28, 2018) (*in camera*) [redacted]

4001. {[redacted] (PX2078 (Illumina) at 001 (Email from M. Van Oene, Illumina, to N. Berry, Illumina, Feb. 28, 2018) (*in camera*) [redacted]

4002. {[redacted] (PX7052 (Leite (Illumina) IHT at 136-37) (*in camera*)).

4003. [redacted]} (*See* PX2617 (Illumina) at 005 (Email from M. Bornstein, Illumina, to Legal Contracts, Illumina, attaching IVD Test Kit Development Agreement, Nov. 4, 2020) ([redacted]}) (*in camera*); PX7049 (Bailey (PGDx) IHT at 123-24) (*in camera*) ([redacted])).

(a) Because PGDx Could Not Get an IVD Agreement from Illumina PGDx Found a Novel Way to Gain FDA Approval by Running the Elio Tissue Complete Test in RUO Mode with a Quality Control Software

4004. When Illumina refused to provide PGDx with an IVD agreement, PGDx had discussions with the FDA on pursuing another viable path. (PX7049 (Bailey (PGDx) IHT at 96-97) ("the broad understanding within the company at the time I joined it, actually, was that PGDx had sought an IVD agreement with Illumina and was unable to obtain one and then began the discussions with the FDA on what another viable path might look like.")). [redacted]} (PX7112 (Bailey (PGDx) Dep. at 48-49); PX7049 (Bailey (PGDx) IHT at 96-99) (*in camera*)).

4005. [redacted] (PX7049 (Bailey (PGDx) IHT at 98-99) (*in camera*)).

4006. [redacted] (PX7049 (Bailey (PGDx) IHT at 103-04 (*in camera*))). [redacted] (PX7049 (Bailey (PGDx) IHT at 103-04 (*in camera*))).

4007. [redacted] (PX7049 (Bailey (PGDx) IHT at 104 (*in camera*)). [redacted] (PX7049 (Bailey (PGDx) IHT at 104 (*in camera*))).

4008. [redacted] (PX7049 (Bailey (PGDx) IHT at 105) (*in camera*)).

4009. More specifically, PGDx's direct collaboration with the FDA took between six to twelve months with "multiple months of alignment meetings with [] the FDA on the approach itself and then probably another three to six months of product development around the software device." (PX7112 (Bailey (PGDx) Dep. at 51)).

4010. [redacted] (PX7049 (Bailey (PGDx) IHT at 104-05) (*in camera*)).

4011. [redacted] (PX7049 (Bailey (PGDx) IHT at 105-06) (*in camera*)).

(i) PGDx's Customers and Investors Raised Concerns About PGDx Not Having an IVD Agreement Which Pushed PGDx to Reengage Negotiations with Illumina

4012. Ms. Bailey testified that PGDx's customers reacted to the Elio Tissue Complete workaround test running in RUO mode "fine" "from a workflow perspective." But "there [were] some usability enhancements if you are in the IVD software mode in the sense that it's a straightforward dropdown to select the test. But [running the Elio Tissue Complete test in RUO mode] is not [] extremely cumbersome, it's not just as straightforward as the other path." (PX7112 (Bailey (PGDx) Dep. at 51)).

4013. Ms. Bailey testified that "concern expressed by several prospective customers around why we needed the workaround and what our relationship was with Illumina that caused some concern in utilizing the test." (PX7112 (Bailey (PGDx) Dep. at 51-52)). Ms. Bailey learned of this concern by "direct feedback" from customers as "usually a member of [PGDx's] sales team, or, in some cases, customer support team that would hear the feedback and get questions directly from customers." (PX7112 (Bailey (PGDx) Dep. at 52)).

4014. Ms. Bailey testified that customers were concerned about PGDx's workaround and the relationship PGDx had with Illumina because "there was mention by Illumina representatives in those laboratories that PGDx didn't have a license to the platform or that they could be violating terms and conditions of their relationship by utilizing our test." (PX7112 (Bailey (PGDx) Dep. at 52)).

4015. Ms. Bailey testified that besides a license and the ability to use Illumina's products there were no concerns from customers about the results of the RUO software workaround test. (PX7112 (Bailey (PGDx) Dep. at 52)).

4016. Ms. Bailey testified that there was a concern regarding licensing of the Illumina platform which "was prompted by discussions with those laboratory [customers] from members of the Illumina field team." (PX7112 (Bailey (PGDx) Dep. at 53)). Specifically, "there was mention by Illumina representatives in those laboratories that PGDx didn't have a license to the platform or that they could be violating terms and conditions of their relationship by utilizing [PGDx's] test." (PX7112 (Bailey (PGDx) Dep. at 52)).

4017. The PGDx customer concern was "prompted by discussions with those laboratories from members of the Illumina field team." (PX7112 (Bailey (PGDx) Dep. at 53)).

4018. Ms. Bailey testified that the concern she "typically heard expressed was more whether the customer would be violating anything around the terms and conditions of their contractual relationship with Illumina by using [PGDx's] product that had a workaround approach." (PX7112 (Bailey (PGDx) Dep. at 53)).

4019. PGDx's pharmaceutical customers did not want to pursue an Illumina IVD rights workaround telling PGDx that "they would not consider a companion diagnostic program with [PGDx] without an IVD co-development agreement." (PX7049 (Bailey (PGDx) IHT at 111)).

4020. Customers indicated to Dr. Leite in negotiations that they placed value on the reputational signal that an IVD agreement with Illumina would send to payers and pharmaceutical companies. (Leite (Illumina) Tr. 2183).

4021. [redacted] } (PX2095 (Illumina) at 004 [redacted] (*in camera*)).

4022. [redacted]

[redacted] }

(PX7049 (Bailey (PGDx) IHT at 108-09) (*in camera*)).

4023. The concern raised by prospective PGDx partners about PGDx's Elio Tissue Complete workaround test was that Illumina would change the platform in some way to make PGDx's tissue test harder to run. (PX7049 (Bailey (PGDx) IHT at 110)).

4024. The concerns raised by PGDx's customers about the Elio Tissue Complete workaround test impacted PGDx's ability to get pharmaceutical partnerships. (PX7049 (Bailey (PGDx) IHT at 111-12)). Ms. Bailey testified that there are "numerous examples of prospective partners saying they would not consider a companion diagnostic program with [PGDx] without an IVD co-development agreement" with Illumina. (PX7049 (Bailey (PGDx) IHT at 111-12)).

4025. Ms. Bailey testified that PGDx's pharmaceutical partners had concerns about "commercial risk" and PGDx was "told directly by multiple pharma partners that they would not enter into a companion diagnostic agreement with PGDx without [an IVD] agreement in place" with Illumina. (PX7112 (Bailey (PGDx) Dep. at 53-54)).

4026. [redacted] (PX7049 (Bailey (PGDx) IHT at 118) (*in camera*)).

4027. [redacted] (PX7049 (Bailey (PGDx) IHT at 118) (*in camera*)).

4028. These pharma partners were large and important customers of PGDx. (PX7112 (Bailey (PGDx) Dep. at 54)).

4029. [redacted] } (PX7049 (Bailey (PGDx) IHT at 118-19) (*in camera*)). { [redacted] } (PX7049 (Bailey (PGDx) IHT at 119) (*in camera*)).

4030. [redacted] (PX7049 (Bailey (PGDx) IHT at 120) (*in camera*)).

4031. It's important for a test to have companion diagnostic capabilities "in the sense that it demonstrates very clearly the clinical utility. Typically, companion diagnostics are supported by a clinical trial positive outcome around the drug efficacy or other means of demonstrating that that patient subset will have a [] better response to the therapy." (PX7112 (Bailey (PGDx) Dep. at 30)).

4032. Ms. Bailey testified that concerns raised by customers regarding the Elio tissue complete workaround test "had a more direct impact to business on the pharma side and among investors." (PX7049 (Bailey (PGDx) IHT at 111-12)). When PGDx went to market without IVD rights from Illumina, PGDx's prospective investors told PGDx "that they would not make an investment without [PGDx] having the IVD co-development agreement with Illumina." (PX7049 (Bailey (PGDx) IHT at 111-12)).

4033. When PGDx went to market without IVD rights from Illumina, PGDx's pharmaceutical customers did not want to pursue an Illumina IVD rights workaround telling PGDx that "they would not consider a companion diagnostic program with [PGDx] without an IVD co-development agreement." (PX7049 (Bailey (PGDx) IHT at 111-12)).

4034. PGDx's CEO, Ms. Bailey, testified that reduced investment decreases PGDx's ability to fund its research and development projects. (PX7112 (Baily (PGDx) Dep. at 195)).

4035. [redacted]

[redacted]} (PX7049 (Bailey (PGDx) IHT at 128) (*in camera*)).

4036. [redacted]} (PX7049 (Bailey (PGDx) IHT at 117-18) (*in camera*)). [redacted] (PX7049 (Bailey (PGDx) IHT at 117-18) (*in camera*)).

4037. The concerns raised by pharmaceutical partners, strategic lab customers, and investors regarding the Elio Tissue Complete workaround test drove PGDx to seek an IVD agreement with Illumina. (PX7112 (Bailey (PGDx) Dep. at 54-55) ("Q. Did these pharma partners' concerns drive PGDx to seek an IVD agreement with Illumina? A. In part. I would say the – those concerns – the feedback expressed by some strategic customers in the lab segment, as well as investors, led PGDx to negotiate the IVD agreement.")).

(ii) Illumina Knows Whether a Customer Is Using PGDx's Test Because of the Reagents They Have to Purchase from Illumina to Run PGDx's Test on Illumina's sequencer

4038. A PGDx customer wanting to run the Elio Tissue Complete test would have to buy the Illumina reagents to run the test directly from Illumina. (PX7049 (Bailey (PGDx) IHT at 175)).

4039. Ms. Bailey testified that because of the "lack of IVD kits on the market outside of PGDx's it is not hard for Illumina to figure out" whether a company ordering Dx reagents is using PGDx's test. (PX7049 (Bailey (PGDx) IHT at 175)). In other words, a customer just ordering the Dx reagents from Illumina would signal that they are using a PGDx test. (PX7049 (Bailey (PGDx) IHT at 175)).

4040. Ms. Bailey testified that some of PGDx's customers tell Illumina what test they are running when purchasing Dx reagents. Specifically, Ms. Bailey mentioned two examples of this occurring: "one that [told us] they were choosing to partner with us for this content over TSO500, so it was discussed openly with the customer, and then the other one was a lab using our test actually as a orthogonal method, a method to compare against for something else they were developing. And when they went to order the DX reagents they described what tests they intended to run on the NextSeq platform." (PX7049 (Bailey (PGDx) IHT at 176)).

4041. Illumina made it difficult for PGDx's customers to buy Illumina Dx reagents needed to run PGDx's test because the test was not subject to an Illumina IVD agreement. Ms. Bailey testified that "on the laboratory [customer] side [PGDx had] a couple instances where the field sales team for Illumina when the customer would go to order the Dx reagents say

PGDx is not licensed to have those products on our platform and make it difficult to order them." (PX7049 (Bailey (PGDx) IHT at 111-12)).

4042. Illumina's sales team knew which customers were running PGDx's test because there is "typically [] somebody like a field application specialist who is in the laboratory who knows what the lab is intending to run and validate and so when that comes up and they know it's our test." (PX7049 (Bailey (PGDx) IHT at 112-13)).

4043. When asked how Illumina would know which of its customers are using Illumina reagents to run PGDx's Elio Tissue Complete workaround test Ms. Bailey explained that Illumina doesn't know "from a centralized corporate standpoint" as the reagents are "an orderable part number, in [a] catalogue. But what can happen is one of two things, either that's a part number that the customer has never needed before because they've never run an IVD cleared product on the platform and so they need to negotiate pricing with Illumina and establish that to be able to order it. Or… a local sales rep or a local support rep is in trying to support the customer and what tests they are onboarding and then they are told what test the lab is planning to run." (PX7049 (Bailey (PGDx) IHT at 113-14)).

(iii) {[redacted]}

4044. [redacted] (PX7063 (Berry (Illumina) IHT at 98) (*in camera*); PX2310 (Illumina) (Email from N. Berry, Illumina, to J. Leite, Illumina, and S. Young, Illumina, May 12, 2020 (*in camera*))).

4045. [redacted] (PX2310 (Illumina) (Email from N. Berry, Illumina, to J. Leite, Illumina, and S. Young, Illumina, May 12, 2020 (*in camera*))).

4046. [redacted] } (PX7063 (Berry (Illumina) IHT at 98-99) (*in camera*)).

4047. [redacted] } (PX7063 (Berry (Illumina) IHT at 99) (*in camera*)). {[redacted]} (PX7063 (Berry (Illumina) IHT at 99) (*in camera*)).

4048. [redacted]

(PX7063 (Berry (Illumina) IHT at 100) (*in camera*) {
}).

4049. (PX2310 (Illumina) (Email from N. Berry, Illumina, to J. Leite, Illumina, and S. Young, Illumina, May 12, 2020 (*in camera*)) (PX7063 (Berry (Illumina) IHT at 101) (*in camera*)).

4050. (PX7063 (Berry (Illumina) IHT at 104-05 (*in camera*)) {
}).

(5) {
}

4051. } (PX2200 (Illumina) at 002 (Email from J. Leite, Illumina, to M. Van Oene et al., Illumina, Nov. 3, 2020 (*in camera*)); PX7049 (Bailey (PGDx) IHT at 95, 125) (*in camera*);. PX2617 (Illumina) at 002 (Email from M. Bronstein, Illumina, to LegalContracts@illumina.com, Nov. 4, 2020) (*in camera*))).

4052. (PX7052 (Leite (Illumina) IHT at 139 (*in camera*))).

4053. (*See* PX2200 (Illumina) at 001 (Email from M. Bornstein, Illumina, to

N. Berry et al., Illumina, Nov. 3, 2020 (*in camera*)) {).

4054. (PX7049 (Bailey (PGDx) IHT at 121, 124) (*in camera*)).

4055. (PX7049 (Bailey (PGDx) IHT at 121-23) (*in camera*) { . *See* PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami, Illumina, Nov. 3, 2020 (*in camera*) { })).

(a) {

4056. } (PX7049 (Bailey (PGDx) IHT at 121) (*in camera*)).

4057. { } (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami et al., Illumina, Nov. 3, 2020 (*in camera*)); PX2617 (Illumina) at 020, 041 (Email from M. Bronstein, Illumina, to LegalContracts@illumina.com, Nov. 4, 2020) (*in camera*)).

(b) {[redacted]}

4058. [redacted]}[.]" (PX2617 (Illumina) at 005 (Email from M. Bronstein, Illumina, to LegalContracts@illumina.com, Nov. 4, 2020) (*in camera*)).

4059. {[redacted]} (PX7049 (Bailey (PGDx) IHT at 123) (*in camera*)).

4060. [redacted] (PX7049 (Bailey (PGDx) IHT at 123) (*in camera*) {[redacted]}).

4061. [redacted]}. (PX2617 (Illumina) at 044 (Email from M. Bronstein, Illumina, to LegalContracts@illumina.com, Nov. 4, 2020) (*in camera*)).

4062. The Elio Tissue Complete test would be at a disadvantage if it could not indicate for TMB. (PX7112 (Bailey (PGDx) Dep. at 26)).

4063. [redacted] (PX7049 (Bailey (PGDx) IHT at 150-152) (*in camera*).

4064. [redacted] (PX7049 (Bailey (PGDx) IHT at 123-24) (*in camera*)).

4065. [redacted] (PX7049 (Bailey (PGDx) IHT at 124, 147) (*in camera*)).

4066. [redacted] (PX7049 (Bailey (PGDx) IHT at 138, 141) (*in camera*)).

4067. [redacted] (PX7049 (Bailey (PGDx) IHT at 124 (*in camera*) {[redacted]}).

4068. [redacted] (Leite (Illumina) Tr. 2099-2100 (*in camera*)).

4069. [redacted] (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami et al., Illumina, Nov. 3, 2020 (*in camera*))).

4070. [redacted] Leite (Illumina) Tr. 2100 (*in camera*)).

(c) {[redacted]}

4071. [redacted] (PX7049 (Bailey (PGDx) IHT at 125) (*in camera*)).

4072. [redacted]} (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami et al., Illumina, Nov. 3, 2020 (*in camera*)); PX7049 (Bailey (PGDx) IHT at 125 (*in camera*)). *See* PX7112 (Bailey (PGDx) Dep. at 86 (*in camera*)) {[redacted]}).

(d) {[redacted]

4073. {[redacted]} (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami et al., Illumina, Nov. 3, 2020 (*in camera*)); PX2617 (Illumina) at 020, 041 (Email from M. Bronstein, Illumina, to LegalContracts@illumina.com, Nov. 4, 2020) (*in camera*)).

4074. [redacted] (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami et al., Illumina, Nov. 3, 2020 (*in camera*))).

4075. [redacted] (PX2211 (Illumina) at 001 (Email from M. Bornstein, Illumina, to J. Goswami, et al. Illumina, Nov. 3, 2020 (*in camera*))).

(e) [redacted]

4076. [redacted] (PX7049 (Bailey (PGDx) IHT at 128) (*in camera*)).

4077. [redacted] (PX7112 (Bailey (PGDx) Dep. at 86) (*in camera*)).

4078. "[redacted]} (PX7112 (Bailey (PGDx) Dep. at 86) (*in camera*)).

4079. [redacted]} (PX7049 (Bailey (PGDx) IHT at 128) (*in camera*)).

4080. [redacted] (PX7049 (Bailey (PGDx) IHT at 128-129); PX7112 (Bailey (PGDx) Dep. at 86-87) (*in camera*)).

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

a) NIPT Overview

4081. [redacted] (PX7113 (Rabinowitz (Natera) Dep. at 36) (*in camera*)).

4082. Dr. Dennis "Lo was the first scientist to discover the presence of circulating fetal DNA in a pregnant mother's blood." (PX4613 (Grail) at 002 (E-mail from V. Bajaj, Grail, to science_organization@grailbio.com, May 31, 2017)).

4083. NIPT was one of the first applications of NGS in a clinical setting. (PX7089 (Naclerio (Illumina) Dep. at 42)).

4084. [redacted] (PX7071 (Song (Omniome) IHT at 66–67) (*in camera*)).

4085. [redacted] } (PX7071 (Song (Omniome) IHT at 67) (*in camera*)).

4086. [redacted] } (PX7071 (Song (Omniome) IHT at 67–68) (*in camera*)).

4087. {[redacted]} (PX7071 (Song (Omniome) IHT at 68) (*in camera*)).

4088. [redacted] } (PX7054 (Rabinowitz (Natera) IHT at 36–38) (*in camera*)).

4089. [redacted] (PX7113 (Rabinowitz (Natera) Dep. at 36-37) (*in camera*)).

4090. NIPT has largely replaced invasive tests like amniocentesis and CVS. (PX7113 (Rabinowitz (Natera) Dep. at 22-23)).

b) Illumina Acquired Verinata in 2013

4091. In 2010, prior to the launch of the first NIPT test and prior to its acquisition of Verinata, Illumina considered different options of how it would participate in the NIPT market. (PX2266 (Illumina) at 002 (E-mail from K. Dobie, Illumina, to N. Naclerio, Illumina, attaching "Opportunity Review Board Meeting Minutes 100930," Oct. 8, 2010)).

4092. One option for participating in the NIPT market that Illumina's Opportunity Review Board considered in 2010 was to become an "arms dealer." (PX2266 (Illumina) at 002 (E-mail from K. Dobie, Illumina, to N. Naclerio, Illumina, attaching "Opportunity Review Board Meeting Minutes 100930,"Oct. 8, 2010)). Being an "arms dealer" referred to selling

instruments to NIPT companies and allowing the NIPT companies to compete among themselves. (PX7060 (Naclerio (Illumina) IHT at 48)).

4093. Another option for participating in the NIPT market that Illumina's Opportunity Review Board considered in 2010 was to become a "consolidator." (PX2266 (Illumina) at 002 (E-mail from K. Dobie, Illumina, to N. Naclerio, Illumina, attaching "Opportunity Review Board Meeting Minutes 100930,"Oct. 8, 2010)). Becoming the "consolidator" referred to Illumina acquiring a NIPT company and competing in NIPT itself. (PX7060 (Naclerio (Illumina) IHT at 48)).

4094. Dr. Naclerio testified that prior to Illumina's acquisition of Verinata, "[i]t was clear that NIPT was going to be a really big business." (PX7060 (Naclerio (Illumina) IHT at 51)).

4095. Before being acquired by Illumina, Verinata "competed with some of [Illumina's] other customers." (PX7057 (Flatley (Illumina) IHT at 15)).

4096. Illumina acquired Verinata in 2013. (PX7089 (Naclerio (Illumina) Dep. at 41, 80–81)).

4097. Illumina paid approximately $450 million to acquire Verinata. (PX7060 (Naclerio (Illumina) IHT at 56)). The sum Illumina paid for Verinata was "a very big deal" to Illumina at the time. (PX7060 (Naclerio (Illumina) IHT at 56)).

4098. At the time of Illumina's acquisition of Verinata, "[r]apid NIPT adoption [was] a common phenomenon across [the United States.]" (PX2432 (Illumina) at 002 (E-mail from N. Naclerio, Illumina, to E. Cheung, Illumina, et al., Feb. 1, 2013)).

(1) Background on NIPT Intellectual Property Disputes

4099. Prior to Illumina's acquisition of Verinata, there was IP-related litigation among the NIPT companies. (PX7060 (Naclerio (Illumina) IHT at 51)).

4100. There came a time when it appeared that Verinata's IP would "be the stronger IP." (PX7060 (Naclerio (Illumina) IHT at 52)).

4101. It appeared that the IP disputes were "settling out in favor of Verinata." (PX7089 (Naclerio (Illumina) Dep. at 50)).

4102. In an October 2012 board presentation, Dr. Naclerio proposed that Illumina could "[a]cquire [a] dominant IP position" by acquiring Verinata. (PX2270 (Illumina) at 012 (Email from N. Naclerio, Illumina, to A. Pierce et al., Illumina, attaching "Corporate & Venture Development Update," Oct. 25, 2012)).

c) NIPT Market Overview

(1) Market Participants at the Time of Illumina's Acquisition of Verinata

4103. At the time that Illumina acquired Verinata, four companies provided NIPT in the United States: Sequenom, Verinata, Ariosa, and Natera. (PX7060 (Naclerio (Illumina) IHT at 44)).

4104. At the time that Illumina acquired Verinata, all four companies that provided NIPT in the United States used Illumina's NGS platform. (PX7060 (Naclerio (Illumina) IHT at 44-45)).

4105. Illumina considered a Natera IVD to be competitive with Illumina's own NIPT product. (PX2219 (Illumina) at 024 (Illumina, Review of 2013 Strategic Discussion Topics, Nov. 17, 2014)).

4106. Illumina's ordinary course documents identified Sequenom, Ariosa/Labcorp, Verinata, and Natera as the U.S. "players" in NIPT. (PX2270 (Illumina) at 008 (Illumina, Corporate & Venture Development Update, Oct. 25, 2012) (noting "Illumina is currently the platform supplier to all of the major NIPD players")).

(a) Sequenom

4107. Sequenom launched the first NIPT test in 2011. (PX7071 (Song (Omniome) IHT at 65-66)).

4108. Sequenom's NIPT method relied on random shotgun sequencing. (PX7071 (Song (Omniome) IHT at 65-66)).

4109. Sequenom was acquired by Labcorp in 2016. (PX7122 (Eisenberg (Labcorp) Dep. at 76–77)).

(b) Verinata

4110. Verinata launched its NIPT test in early 2012. (PX7071 (Song (Omniome) IHT at 66)).

4111. Verinata's NIPT method relied on random shotgun sequencing. (PX2270 (Illumina) at 007 (Illumina, Corporate & Venture Development Update, Oct. 25, 2012)).

(c) Ariosa

4112. Ariosa, another NIPT company, was founded in late 2009. (PX7071 (Song (Omniome) IHT at 61)).

4113. Ariosa launched its NIPT test in 2012. (PX7071 (Song (Omniome) IHT at 64)).

4114. Ariosa's NIPT test relied on Illumina's NGS platform. (PX7071 (Song (Omniome) IHT at 66)).

4115. Dr. Song testified that Ariosa was able to price its NIPT test $2,000 lower than the two existing NIPT tests because "[Ariosa] had developed a targeted approach where [its]

consumption of Illumina sequencing reagents was . . . tenfold lower" than the existing NIPT tests from Sequenom and Verinata. (PX7071 (Song (Omniome) IHT at 69–70)).

4116. Ariosa's ability to use less sequencing for NIPT was "not well received by Illumina." (PX7071 (Song (Omniome) IHT at 70)).

(d) Natera

4117. Natera first launched Panorama in March 2013. (Rabinowitz (Natera) Tr. 289).

4118. {[redacted]} (Rabinowitz (Natera) Tr. 352 (*in camera*)).

4119. [redacted] (Rabinowitz (Natera) Tr. 315-318 (*in camera*)).

4120. At the time Natera launched Panorama, Verinata, Sequenom, and Ariosa were also providing NIPT tests in the United States. (Rabinowitz (Natera) Tr. 290).

4121. {[redacted]} (Rabinowitz (Natera) Tr. 327 (*in camera*)).

4122. [redacted] (Rabinowitz (Natera) Tr. 327 (*in camera*)).

4123. [redacted] (PX2759 (Illumina) at 005 [redacted] (*in camera*)).

(2) [redacted]}

4124. [redacted] (PX2077 (Illumina) at 004 (Strategic approach to shaping the NIPT market, Mar. 11, 2013)). [redacted]} (PX2077 (Illumina) at 004 (Strategic approach to shaping the NIPT market, Mar. 11, 2013)).

4125. [redacted]

4126. [redacted]

4127. [redacted]

[redacted]

4128. [redacted]

4129. [redacted]

4130. [redacted]

4131. [redacted]

4132. [redacted]

4133. [redacted]

4134. [redacted]

4135. [redacted]

4136. [redacted]

4137. [redacted]

(a) [redacted]

4138. [redacted]

4139. [redacted]

4140. [redacted]

[redacted]

4141. [redacted]

4142. [redacted]

4143. [redacted]

4144. [redacted]

4145. [redacted] (PX7060 (Naclerio (Illumina) IHT at 154-155) (*in camera*)).

4146. [redacted] (PX7060 (Naclerio (Illumina) IHT at 127-128) (*in camera*)).

4147. [redacted] (PX2265 (Illumina) at 002 (E-mail from J. Eidel, Illumina, to C. Henry, Illumina, Dec. 11, 2015) (*in camera*)).

4148. [redacted] (PX7060 (Naclerio (Illumina) IHT at 154-155) (*in camera*)).

4149. [redacted] (PX7089 (Naclerio (Illumina) Dep. at 243-244) (*in camera*)).

4150. [redacted]

4151. [redacted]

4152. [redacted] (PX2267 (Illumina) (Email from J. Eidel (Illumina) to J. Flatley et al., Nov. 14, 2015) (*in camera*)).

4153. [redacted] (PX2265 (Illumina) at 002 (Email from J. Eidel (Illumina) to C. Henry et al., Dec. 11, 2015) (*in camera*)).

4154. [redacted]

4155. [redacted]

4156. [redacted]

4157. [redacted]

4158. [redacted] (PX2075 (Illumina) at 007 (Natera Executive Summary, Sept. 30, 2016) (*in camera*)).

4159. [redacted]

[redacted]} (PX7060 (Naclerio (Illumina) IHT at 159–160) (*in camera*)).

4160. {[redacted]} (PX2761 (Illumina) (Email from A. Wellend, Illumina, to S. Rohatgi, Illumina, Jun. 20, 2017) (*in camera*)).

4161. [redacted]} (PX2761 (Illumina) (Email from A. Wellend, Illumina, to S. Rohatgi, Illumina, Jun. 20, 2017) (*in camera*)).

(b) {[redacted]

4162. {[redacted]

4163. [redacted]

4164. [redacted]

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

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

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

4165. [redacted]} (PX7136 (Guerin-Calvert Dep. at 106) (*in camera*)).

4166. [redacted]} (PX7136 (Guerin-Calvert Dep. at 106-07) (*in camera*)).

4167. Ms. Guerin-Calvert testified at her trial deposition that whether a behavioral or conduct remedy is appropriate is "case-specific" and "[t]here may be a vertical merger where a behavioral remedy is not effective." (RX6002 (Guerin-Calvert Trial Dep. at 117)).

4168. [redacted] (PX7136 (Guerin-Calvert Dep. at 20) (*in camera*)).

4169. [redacted] (PX7136 (Guerin-Calvert Dep. at 21) (*in camera*)).

4170. [redacted] (PX7136 (Guerin-Calvert Dep. at 21-22) (*in camera*)).

4171. [redacted] (PX7138 (Scott Morton Trial Dep. at 79) (*in camera*)).

4172. [redacted] (PX7138 (Scott Morton Trial Dep. at 81) (*in camera*)).

4173. As noted in the Department of Justice's 2020 Merger Remedies Manual, when a remedy requires that a supplier help its customers compete against itself, "it is unlikely to exert much effort to ensure the products or inputs it supplies are of high quality, arrive as scheduled, match the order specifications, and satisfy other conditions that are necessary to preserve competition." (RX3702 (U.S. Dep't of Justice, Antitrust Division, Merger Remedies Manual (Sept. 2020) at 14.

4174. One key issue with remedying mergers through long-term supply agreements is that "[c]ontractual terms are difficult to define and specify with the requisite foresight and precision". (RX3702 (U.S. Dep't of Justice, Antitrust Division, Merger Remedies Manual (Sept. 2020) at 14)).

a) The Open Offer Cannot Change Illumina's Strong Incentives to Favor Grail

4175. [redacted] (PX7138 (Scott Morton Trial Dep. at 74-75) (*in camera*)).

4176. [redacted] (PX7138 (Scott Morton Trial Dep. at 74-75) (*in camera*)).

4177. Singlera's Dr. Gary Gao testified that Illumina has an "inherent conflict of interest" when it comes to Grail:

> [I]f GRAIL was not started by Illumina, Illumina has no stake in any screening company. Things could be different. Then Illumina will wish many company succeed so they can supply the machine and reagent. But because of GRAIL, Illumina may want to have GRAIL succeed, other company slow down. There's no incentive for Illumina to support other people other than GRAIL.

(PX7042 (Gao (Singlera) IHT at 89-90)).

4178. [redacted]

4179. [redacted]

4180. [redacted] (PX6090 (Scott Morton Report) ¶ 306 (*in camera*)).

4181. [redacted] (*See* PX6091 (Scott Morton Rebuttal Report) ¶¶ 98-100 (*in camera*)).

4182. Pre-Acquisition, Illumina claimed its objective was to "maximize customer success and satisfaction." (PX7076 (Berry (Illumina) Dep. at 105-06)).

4183. [redacted]

[redacted]

4184. [redacted]

4185. Guardant's Senior Vice President of Commercial, William Getty, testified that after the acquisition, Illumina's "incentive to work with us goes down almost to nothing because ultimately we will now be competing in the same market, and therefore Illumina, as they should, will want to maintain a competitive advantage over Guardant in that space." (PX7105 (Getty (Guardant) Dep. at 68-69)).

4186. Mr. Getty testified that he does not think a contract between Guardant and Illumina could eliminate Illumina's incentives to favor Grail. (PX7105 (Getty (Guardant) Dep. at 79-80)).

4187. Mr. Getty expressed concern about Illumina post-acquisition, testifying:

> [I]n the future state, if you – if your competitor is part of your own organization and you actually want them to be highly competitive, then you have all the incentive in the world to optimize their information ahead of their competitive set and you have potentially – not potentially – you likely have significant financial ties associated with that competitive advantage.

(PX7105 (Getty (Guardant) Dep. 100-01)).

4188. Mr. Getty testified that the acquisition would shift Illumina's incentives:

> [T]he assumption here is that, again, it's in [Illumina's] best interest to keep Guardant happy as a customer. However, if your business is no longer sequencing, then why is it that you would want to keep Guardant happy per se, right. You would want to actually move them out of the market so you could have a bigger share of the market. That's the underlying concern at the heart of all of this.

(PX7040 (Getty (Guardant) IHT at 189)).

4189. [redacted]

4190. [redacted]

[redacted]

4191. At trial, Guardant's Mr. Getty testified that he expects Illumina's incentives towards Guardant will change when Illumina becomes a competitor to Guardant rather than only a supplier. (Getty (Guardant) Tr. 2681-82). Mr. Getty explained the changing incentives, "[C]urrently the [MCED test] marketplace has been estimated to be, you know, $50 billion-plus. . . It's the largest market available to probably [Illumina and Guardant]" and, for Illumina, "the incentives will be there in order to tap into that much larger market than what is available today because that's going to increase shareholder value ostensibly." (Getty (Guardant) Tr. 2681-82).

4192. Respondents' economic expert, Dr. Willig, testified, "if the incentives aren't right, then the contract is not going to be successful . . . the parties try to build in the protection that they think they can get into the contract, but the real details of how the business is going to work evolve from appropriate business incentives shared by the parties." (PX7132 (Willig Dep. at 289-290)).

4193. [redacted] (PX6090 (Scott Morton Report) ¶ 229 (*in camera*); PX6091 (Scott Morton Rebuttal Report) ¶ 102 (*in camera*)).

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

a) Illumina Sought Long Term Supply Agreements with Grail's Key Competitors

(1) Illumina's Initial Outreach to Customers Re Illumina's Acquisition of Grail

4194. In September 2020, Illumina's Nicole Berry was "involved in a proactive reach-out program with a select group of customers" to discuss Illumina's proposed acquisition of Grail. (PX7063 (Berry (Illumina) IHT at 123-24)).

4195. Illumina created a "stratification of customers that would be prioritized for proactive reach-out." (*See* PX7063 (Berry (Illumina) IHT at 124); *see also* PX2302 (Illumina) (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020)).

4196. In a September 21, 2020 email, Ms. Berry explained to Mr. Fiedler and Mr. Gallad that Illumina has "identified a number of customers whom we believe it would be good to reach out proactively regarding the GRAIL announcement." (PX2302 (Illumina) at 001 (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020)).

4197. Ms. Berry's email broke down Illumina customers into "Tier 1 customers" and "Tier 2 customers." (PX2302 (Illumina) at 001-002 (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020)).

4198. Ms. Berry's email stated that "Tier 1 customers" were to be contacted by "Francis [deSouza] and MVO, [Mark Van Oene], to assist with, as either our largest onc[ology] testing customers or those specifically participating in the early detection space." (PX2302 (Illumina) at 001 (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020)).

4199. [redacted] (PX2302 (Illumina) at 001-002 (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020) (*in camera*)).

4200. In Ms. Berry's September 21, 2020 email, she highlighted in yellow below the "Tier 1 customers" chart that

> The primary purpose of these calls is to assure these customers that the GRAIL transaction will have no impact on Illumina's relationship with the customer, explain to the customer how the transaction will benefit them, and that upon closing of the transaction Illumina will offer the customer a long-term extension of its supply agreement that guarantees access to Illumina's platforms, consumables and service/repair, price decreases, volume discounts and any innovations/improvements to Illumina's instruments and consumables.

(PX2302 (Illumina) at 002 (Email from N. Berry, Illumina to C. Fiedler and M. Gallad, Illumina, Sept. 21, 2020)).

4201. [redacted] } (Berry (Illumina) Tr. 938 (*in camera*)). { [redacted] } (Berry (Illumina) Tr. 938 (*in camera*)).

4202. [redacted] } (Berry (Illumina) Tr. 752-53) (*in camera*). [redacted] } (Berry (Illumina) Tr. 753) (*in camera*)).

4203. [redacted] (Berry (Illumina) Tr. 753-55) (*in camera*)).

(2) Ms. Berry's Contribution to the Customer Outreach List

4204. Although Ms. Berry denied creating the tiers of customers she wrote about in her September 21, 2020 email, Ms. Berry testified that she contributed by "filling out a spreadsheet where I provided inputs. That would then translate to a subsequent stratification." (PX7063 (Berry (Illumina) IHT at 125)).

4205. Ms. Berry's "inputs" included information about Illumina customers' "annual revenue," "priority" category, "freeform inputs," and "commentary." (PX7063 (Berry (Illumina) IHT at 125)).

4206. Illumina's "priority" classification indicated "whether [Illumina] felt that a specific customer should be prioritized for proactive reach-out. And if so, by whom, because we -- I believe -- my recollection is that we had -- we had proactive reach-out for a couple of different layers, if you will, or priority groups, but those reach-outs would be done by different people." (PX7063 (Berry (Illumina) IHT at 126)).

4207. Illumina customers that had business in the oncology space were prioritized for reach-out calls by Illumina executives regarding Illumina's proposed acquisition of Grail. (PX7063 (Berry (Illumina) IHT at 127)).

4208. After Illumina decided which customers to reach out to, Illumina "scheduled calls and executed those calls via videoconference." (PX7063 (Berry (Illumina) IHT at 129-30)).

4209. Illumina reached out to Foundation Medicine, Natera, Guardant Health, Invitae, Thrive, Freenome, Exact Sciences, and LabCorp. (PX7063 (Berry (Illumina) IHT at 130)).

4210. Several Illumina executives participated on these calls including Ms. Nicole Berry, Ms. Kathy Davy, the customer's Illumina account manager, an Illumina commercial organization member, Mr. Francis deSouza, and Mr. Mark Van Oene. (PX7063 (Berry (Illumina) IHT at 130-31)).

(3) Illumina's Ms. Berry, the Signatory on Long-Term Supply Agreements, Expressed Concerns with Illumina Purchasing Grail

4211. {[redacted]} (*See* PX0064 at 002 (Illumina, Open Offer Letter, Mar. 29, 2021); *see, e.g.*, PX2538 (Illumina) at 004 [redacted] (*in camera*); *see, e.g.*, PX2306 (Illumina) at 013 [redacted] (*in camera*)).

4212. Nicole Berry, Illumina's Senior Vice President and General Manager of the Americas Commercial Region, testified at trial that she first learned about Illumina's proposed acquisition of Grail in March 2020. (PX7063 (Berry (Illumina) IHT at 110); Berry (Illumina) Tr. 687)).

4213. In March 2020, Ms. Berry "attended a portion of a leadership meeting during which M&A candidates were being discussed, and [she] saw GRAIL's name on the list." (PX7063 (Berry (Illumina) IHT at 110)).

4214. When Ms. Berry first heard about the proposed acquisition, she had concerns. (PX7063 (Berry (Illumina) IHT at 110); Berry (Illumina) Tr. 687).

4215. Ms. Berry testified that her concerns over Illumina acquiring Grail included "if and when this acquisition came to pass that some of our customers, you know, would have a reaction that would be – would cause us to have to, you know, exert a lot of time and effort in terms of talking them through it and manage it." (PX7063 (Berry (Illumina) IHT at 110-11)).

4216. Ms. Berry testified that she thought customers would have a reaction to Illumina's acquisition of Grail because "it's a big acquisition" and "customers would [] have questions about, you know, how this acquisition would relate to, you know, their – the commercial relationship that they have established with [Illumina]." (PX7063 (Berry (Illumina) IHT at 111)).

4217. Ms. Berry testified that she anticipated questions from customers about whether Illumina's acquisition of Grail "meant any changes to the commercial relationship that [Illumina] had together, you know, built and were engaged in prior to the acquisition taking place." (PX7063 (Berry (Illumina) IHT at 112)).

4218. Ms. Berry testified that the customers she anticipated would need clarification about Illumina's commercial relationship "would primarily relate to customers in, you know, the – that participate in the oncology space . . . because GRAIL is an oncology-focused company." (PX7063 (Berry (Illumina) IHT at 112-13)).

4219. Ms. Berry testified that when she learned of the acquisition, she thought Illumina's oncology customers would have questions about Illumina's proposed acquisition of Grail because these customers also offer oncology products. (PX7063 (Berry (Illumina) IHT at 113)).

4220. [redacted] (PX2569 (Illumina) at 008 (Illumina, *Executive Session* Presentation, Apr. 28, 2020 (*in camera*))).

4221. [redacted] (PX7063 (Berry (Illumina) IHT at 115); *see* PX2157 (Illumina) (Text message exchange between G. Weightman, Illumina, and N. Berry, Illumina, June 4, 2020) (*in camera*)).

4222. [redacted] (PX2283 (Illumina) at 001 (Text from K. Davy, Illumina, to N. Berry, Illumina, June 4, 2020) (*in camera*)).

4223. [redacted] (PX2283 (Illumina) at 001 (Text from K. Davy, Illumina, to N. Berry, Illumina, June 4, 2020) (*in camera*)).

4224. [redacted] (PX7061 (Davy (Illumina) IHT at 240) (*in camera*)).

4225. [redacted] (PX7061 (Davy (Illumina) IHT at 234) (*in camera*)).

4226. [redacted] (PX2157 (Illumina) (Text message exchange between G. Weightman, Illumina, and N. Berry, Illumina, June 4, 2020) (*in camera*); *see* PX7063 (Berry (Illumina) IHT at 117-23)).

4227. [redacted] (PX2157 (Illumina) (Text message exchange between G. Weightman, Illumina, and N. Berry, Illumina, June 4, 2020) (*in camera*)).

4228. Ms. Berry understood Ms. Weightman's question to mean "pretty much exactly what it says, you know, would our customers, you know, be, quote-unquote, upset, if you will, if we started competing on service." (PX7063 (Berry (Illumina) IHT at 118)).

4229. When Ms. Weightman used the phrase "competing on service," Ms. Berry understood her to mean "participat[ing] in the oncology testing market by offering a service in addition to products, supplying products." (PX7063 (Berry (Illumina) IHT at 118)).

4230. Ms. Berry testified that she agreed with Ms. Weightman's statement that post-acquisition Illumina would be competing with its customers because "if a third party's perception . . . that the only outcome of Illumina acquiring GRAIL and offering oncology testing services was simply that we would be offering oncology testing services, then that would concern me . . . ." (PX7063 (Berry (Illumina) IHT at 119)).

4231. Ms. Berry testified that "[i]n this context, 'service' refers to Illumina processing samples in our laboratory and returning results to the originator of the samples, similar to the Verinata model that I described earlier." (PX7063 (Berry (Illumina) IHT at 118-19)).

4232. Ms. Berry testified that she agreed with Ms. Weightman that post-acquisition of Grail, Illumina would start competing on service with its customers. (PX7063 (Berry (Illumina) IHT at 119-20)).

4233. In a text message dated June 4, 2020, between Ms. Berry and Gretchen Weightman, Illumina's general manager of the Asia Pacific region, Ms. Weightman asked "How much does [G]rail compete with your customers? Would it piss off a ton of your customers if we start competing on service?" Ms. Berry responded "Of course. It would be disastrous." PX2157 (Illumina) at 001 (Mobile text chain between N. Berry, Illumina, and G. Weightman, Illumina, June 4, 2020). [redacted] } (Berry (Illumina) Tr. 740) (*in camera*).

4234. Ms. Berry testified at trial that when she learned about the potential acquisition of Grail in March 2020, she had concerns that her "customers, generally speaking, would perceive this as a shift in Illumina's strategy . . ." (Berry (Illumina) Tr. 687).

4235. Ms. Berry testified that she believed customers would have questions about how the acquisition would impact their commercial relationship with Illumina. (Berry (Illumina) Tr. 688).

4236. In particular, Ms. Berry testified that customer questions regarding the proposed acquisition of Grail would come from oncology customer since public information "clearly identifies [Grail] as being in the oncology testing space." (Berry (Illumina) Tr. 688).

4237. Ms. Berry testified that, in June 2020, she [redacted] (Berry (Illumina) Tr. 740-41) (*in camera*)).

4238. [redacted] } (PX2160 (Illumina) at 006 (Email from T. Boyaniwsky, Illumina, to M. Van Oene, Illumina, and N. Berry, Illumina, et al, attaching Commercial All Hands_3Q20_DRAFT_v2.pptx, Oct. 28, 2020) (*in camera*)).

b) Illumina Sent Letters to a Subset of Its Oncology Customers in Early October 2020 to Announce the Transaction and Provided Information About Illumina's Supply of NGS Products Moving Forward

4239. After Illumina made initial phone calls to select customers, including Guardant, FMI, Natera, Invitae, Thrive, Freenome, and Exact, Illumina followed up by sending letters. (PX7063 (Berry (Illumina) IHT at 130-31)).

4240. [redacted]

(Berry (Illumina) Tr. 755) (*in camera*)).

(Berry (Illumina) Tr. 755-56) (*in camera*)).

4241. On October 9, 2020 Ms. Berry sent letters to Illumina's MCED customers to announce its proposed merger with Grail and provide certain assurances about the Illumina-Grail transaction. (PX7063 (Berry (Illumina) IHT at 131); *see e.g.*, PX2068 (Illumina) at 002-003 (*in camera*)).

4242. Ms. Berry testified that Illumina's legal team drafted the October 9, 2020 letter of intent. (PX7063 (Berry (Illumina) IHT at 132)).

4243. (Berry (Illumina) Tr. 938) (*in camera*).

4244. (Berry (Illumina) Tr. 938) (*in camera*).

4245. Ms. Berry testified that she was not aware of any other time that Illumina has sent a letter of intent relating to an Illumina acquisition to Illumina's customers. (PX7063 (Berry (Illumina) IHT at 141)).

4246. (PX2303 (Illumina) (Email from N. Berry, Illumina, to G. Otte, Freenome, attaching letter of intent, Oct. 9, 2020); PX2645 (Illumina) (*in camera*); PX2651 (Illumina) (*in camera*); PX2068 (Illumina) at 002-003 (*in camera*); PX2644 (Illumina) (*in camera*); PX2649 (Illumina) (*in camera*); PX2648 (Illumina) (*in camera*); PX8349 (Tempus) (Illumina letter to Tempus Labs, Inc. ("Tempus"), Oct. 9, 2020); *see also* PX7056 (Silvis (Tempus) IHT at 66) (*in camera*)).

4247.

[redacted] (*See e.g.*, PX2068 (Illumina) at 002 [redacted] (*in camera*)).

4248. After customers raised concerns that Illumina may share their competitively sensitive information with Grail post-acquisition, Illumina sent out revised letters a few weeks later, adding that Illumina will not share customers' confidential information with Grail. (PX7063 (Berry (Illumina) IHT at 134-135)). Ms. Berry sent Illumina's second letter of intent to select customers on October 20, 2020. (*See e.g.*, PX2067 (Illumina) at 002-003 (Email from N. Berry, Illumina to S. George, Invitae, attaching letter of intent, Oct. 20, 2020)).

4249. [redacted] } (*See* PX2658 (Illumina) at 001 (Email from N. Berry, Illumina, to L. Leigh, Illumina, Oct. 28, 2020) (*in camera*); PX2643 (Illumina) at 002-003 (Email from N. Berry, Illumina, to S. Chapman, Natera, Oct. 20, 2020) (*in camera*)); PX2067 (Illumina) at 002-003 (Email from N. Berry, Illumina to S. George, Invitae, attaching letter of intent, Oct. 20, 2020); PX2664 (Illumina) at 002 (Email from N. Berry, Illumina, to K. Fiedler, FMI, Oct. 20, 2020) (*in camera*); PX2655 (Illumina) [redacted] (*in camera*); PX2642 (Illumina) at 002-003 (Email from N. Berry, Illumina, to M. Eisenberg, LabCorp, Oct. 20, 2020) (*in camera*); PX2653 (Illumina) at 002-003 (Email from N. Berry, Illumina, to A. Elliott, Ambry, Oct. 20, 2020) (*in camera*); PX2650 (Illumina) at 002-003 (Email from N. Berry, Illumina, to D. Spetzler, Caris, Oct. 20, 2020) (*in camera*)).

4250. [redacted] } (Berry (Illumina) Tr. 756-57) (*in camera*)).

(1) Customers Reactions to Illumina's Letters of Intent

(a) Freenome

4251. [redacted] (PX7055 (Otte (Freenome) IHT at 102-03) (*in camera*)).

4252. [redacted] } (PX7055 (Otte (Freenome) IHT at 103-04) (*in camera*)).

4253. [redacted]

} (PX7055 (Otte (Freenome) IHT at 103-04) (*in camera*)).

4254. (PX7055 (Otte (Freenome) IHT at 103-04) (*in camera*)).

4255. (PX7055 (Otte (Freenome) IHT at 113-15) (*in camera*)).

4256. } (PX7055 (Otte (Freenome) IHT at 113-14) (*in camera*)).

4257. (PX7055 (Otte (Freenome) IHT at 113-14) (*in camera*)).

4258. } (PX7055 (Otte (Freenome) IHT at 113-16)) ({ }) (*in camera*)).

4259.

[redacted]

(PX7055 (Otte (Freenome) IHT at 113-6) (*in camera*)).

4260. [redacted] (PX7055 (Otte (Freenome) IHT at 116-17) (*in camera*)).

4261. [redacted] (PX7055 (Otte (Freenome) IHT at 117-18) (*in camera*)).

4262. [redacted] (PX8375 (Freenome) at 003 (Email from G. Otte, Freenome, to M. Nolan et. al, Freenome, Oct. 9, 2020) (*in camera*)).

4263. [redacted] (PX7055 (Otte (Freenome) IHT at 118-19) (*in camera*)).

4264. [redacted] (PX7055 (Otte (Freenome) IHT at 120-11) (*in camera*)).

4265. [redacted]

[redacted]

(PX7094 (Nolan (Freenome) Dep. at 166) (*in camera*)).

4266. [redacted] (PX7094 (Nolan (Freenome) Dep. at 165-67) (*in camera*)).

4267. [redacted] (PX7055 (Otte (Freenome) IHT at 129-30) (*in camera*)).

4268. [redacted] (PX7055 (Otte (Freenome) IHT at 129) (*in camera*); PX8375 (Freenome) at 001 (Email from G. Otte, Freenome, to M. Nolan et. al, Freenome, Oct. 9, 2020) (*in camera*)).

4269. [redacted] (PX7055 (Otte (Freenome) IHT at 129-30) (*in camera*)).

4270. [redacted] (PX7055 (Otte (Freenome) IHT at 130) ([redacted]) (*in camera*)).

c) Concerns Regarding Illumina's Acquisition of Grail Expressed by Illumina Customers

(1) [redacted]

4271. [redacted]

4272. [redacted]

4273. [redacted]

[redacted]

4274. [redacted]

4275. [redacted]

4276. [redacted]

(2) {[redacted]}

4277. [redacted]

4278. [redacted]

4279. [redacted]

[redacted]

4280. [redacted]

4281. [redacted]

4282. [redacted]

4283. [redacted]

4284. [redacted]

4285. [redacted]

4286. [redacted]

[redacted]

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4290. [redacted]

4291. [redacted]

4292. [redacted]

4293. [redacted]

[redacted]

4294. [redacted]

4295. [redacted]

4296. [redacted]

4297. [redacted]

4298. [redacted]

4299. [redacted]

4300. [redacted]

4301. [redacted]

4302. [redacted]

[redacted]

(3) Guardant's Concerns

4303. Illumina's acquisition of Grail "presents a challenge on multiple fronts to Guardant." (PX7040 (Getty (Guardant) IHT at 160)).

4304. Illumina's acquisition of Grail "challenges [Guardant's] ability to be successful as a company in the screening market. And interestingly enough, it also challenges [Guardant's] ability to be competitive in any other portion of the market, because if we see on portion of the business fail, it could have such a negative impact on the broader organization and the market cap of the organization because [Guardant is] not in that business that, you know, the fuel for even those smaller opportunities like therapy selection are irreparably harmed, and therefore, patients are as well because there's just not as many opportunities." (PX7040 (Getty (Guardant) IHT at 160)).

4305. Illumina could hinder Guardant's ability to compete in the screening market in at least three critical ways: first, Illumina could increase the pricing for Guardant's non-screening oncology product, for example, Guardant360, which can hamstring the dollars Guardant can push towards screening. (PX7040 (Getty (Guardant) IHT at 161). Second, Illumina could gain visibility into Guardant's business. Mr. Getty testified that Illumina "could very easily have an advantage to understand what it is [Guardant's] doing, what type of volume… and then target accordingly." (PX7040 (Getty (Guardant) IHT at 161-62). Third, in the downstream distribution of Guardant's screening test Illumina could hinder the distribution of a kitted Guardant product. (PX7040 (Getty (Guardant) IHT at 162)).

4306. Guardant's Mr. Getty testified that he has concerns about Guardant's "reliance on Illumina, and the cost of that reliance is significant." (PX7040 (Getty (Guardant) IHT at 133-34, 162) ("Illumina controls Guardant as much as anything… because it's inescapable to move away from Illumina")).

4307. Mr. Getty is concerned that post-acquisition "Illumina will be acutely aware of [Guardant's] development exercises by simply knowing what [Guardant is] purchasing from them." (PX7040 (Getty (Guardant) IHT at 133-34)). Illumina could then "easily [] increase the cost" of its products "such that [Guardant] couldn't pursue that new development" and therefore would be "less competitive with [Guardant's] product." (PX7040 (Getty (Guardant) IHT at 133-34)).

4308. Mr. Getty is concerned that post-acquisition, Illumina would be able to interfere in Guardant's efforts to improve the sensitivity and innovation of its cancer tests. (PX7040 (Getty (Guardant) IHT at 136-38)).

4309. Mr. Getty is further concerned with acquisition's "downstream impact" on patients because patients would "not have a product that was most sensitive, that could find the disease early and help treat those patients." (PX7040 (Getty (Guardant) IHT at 135)).

4310. Mr. Getty is also concerned with what he calls a more "nefarious potential" of Illumina's acquisition of Grail:

> [Where] you have a competitor who controls essentially your margins, and so, you know – and they – and internally Illumina obviously, you know, wants the most profitable product and can do things at a lower cost because they are the manufacturer of the reagent, and so not only could they copy what [Guardant is] doing, they could do it at a lower cost, maximize their own profitability, and slowly squeeze [Guardant] into a position of being completely uncompetitive or, you know, potentially not able to support the innovation that [Guardant] would need or the innovation [Guardant would] want to pursue.

(PX7040 (Getty (Guardant) IHT at 135)).

4311. As relating to Guardant's LUNAR-2 test Guardant has concerns because the cancer screening market is the "absolute golden goose" and "the underpinning of a lot of companies' valuations" including Guardant's. (PX7040 (Getty (Guardant) IHT at 158-9)).

4312. Mr. Getty testified that he had concerns that the proposed acquisition between Illumina and Grail would have an impact on the cancer screening market as a whole:

> [I]f you take aside Guardant Health, as a, you know, business, let's imagine for a moment that, you know, we never make it into the screening game. We decide for whatever reason we don't pursue it. The acquisition of Grail by Illumina impacts every other company out there pursuing these technologies in the same way it could potentially disenfranchise Guardant. But the impact of that is real. It's patients that are actually impacted. And so by creating this sort of vertically integrated diagnostic player, you've taken the incentives out of the market for all these other companies to pursue the technologies.

(PX7040 (Getty (Guardant) IHT at 179-81)).

4313. Mr. Getty testified that his concerns over the proposed acquisition are heightened because there is no replacement for Illumina and there will not be anytime soon, so "it means that, you know, the whole of patients will be negatively impacted." (PX7040 (Getty (Guardant) IHT at 181)).

4314. Mr. Getty has concerns about Illumina and Grails combined intellectual property portfolio post-acquisition. (PX7040 (Getty (Guardant) IHT at 192-93) (stating that "intellectual property is a very important component" and "it forms a moat for others to have – to have

to penetrate in order to, you know, be a formidable competitor. And so, you know, the intersection of the IP associated with a company who owns all the underlying technology and then, you know, potentially layering on additional patents on top of that, you know, it creates a rather challenging dynamic for other companies to potentially develop competing modalities that leverage that underlying technology because there's an intersection there")).

4315. Mr. Getty testified that he anticipates that the Illumina-Grail intellectual property portfolio will impact Guardant's decisions on innovating going forward. (PX7040 (Getty (Guardant) IHT at 193) (adding that "in large part everyone is dependent on Illumina," and that if Illumina were to "suggest that there is some, you know, infringement ongoing," that "[i]t just may stop you in your track to say, Wow, we can't afford to fight with them")).

4316. Illumina asked Guardant to sign a disclosure saying that Guardant was not concerned about Illumina's proposed acquisition of Grail. (PX7040 (Getty (Guardant) IHT at 190)).

4317. Illumina sent Guardant this disclosure at the beginning of 2021. (PX7040 (Getty (Guardant) IHT at 191)).

4318. Illumina's Mr. Welland drafted Illumina's disclosure that it sent to Guardant. (PX7040 (Getty (Guardant) IHT at 191)).

4319. Guardant did not sign Illumina's disclosure because they "have some major concerns with the acquisition of Grail." (PX7040 (Getty (Guardant) IHT at 192)).

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4367. When the Illumina-Grail transaction was announced it was Mr. Conroy's expectation that Exact could reach a long-term supply agreement that would be in the mutual best interests of both Illumina and Exact. (Conroy (Exact) Tr. 1723-24).

4368. Mr. Conroy and Mr. deSouza had met on several different occasions and had several conversations. (Conroy (Exact) Tr. 1724).

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4452. Guardant had a supply agreement with Illumina prior to Illumina announcing its intent to acquire GRAIL. (PX7040 (Getty (Guardant) IHT at 176-77)).

4453. Guardant's pre-existing supply agreement covers Illumina sequencers, reagents, and service. (PX7040 (Getty (Guardant) IHT at 176)).

4454. [redacted] (Berry (Illumina) Tr. 762) (*in camera*)).

4455. [redacted] (PX2305 (Illumina) at 001 (Email from N. Berry, Illumina, to M. Kreitzinger, Illumina, Oct. 29, 2020) (*in camera*)).

4456. {[redacted]} (PX7040 (Getty (Guardant) IHT at 182); PX2306 (Illumina) at 008 [redacted] (*in camera*)).

4457. Mr. Getty testified that Guardant did not actually engage in "true negotiation" with Illumina over the supply agreement. (PX7040 (Getty (Guardant) IHT at 182).

4458. Mr. Getty testified that Guardant's supply agreement with Illumina entered into in January 2021 does not have audit rights which makes enforceability of the contract a challenge. (PX7040 (Getty (Guardant) IHT at 184)).

4459. [redacted] (PX7105 (Getty (Guardant) Dep. at 77) (*in camera*)).

4460. [redacted] (PX7105 (Getty (Guardant) Dep. at 77-78) (*in camera*) ({ [redacted] })).

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4461. [redacted] (Berry (Illumina) Tr. 761) (*in camera*)).

4462. {[redacted]} (PX8396 (Roche/FMI) [redacted] (*in camera*)).

4463. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 93) (*in camera*); *see* PX7118 (Fiedler (FMI) Dep. at 11)).

4464. Mr. Fiedler testified that it is important to secure supply for FMI's tests "[b]ecause [FMI] serve[s] several hundred thousand patients every year and it is important, and patients are waiting for the results because the results might determine the – how their treatment plan looks like, and therefore, every day counts." (PX7118 (Fiedler (FMI) Dep. at 12)).

4465. FMI would have to shut down its business if it did not have a continued supply of Illumina products. (PX7118 (Fiedler (FMI) Dep. at 12-13)).

e) [redacted]

4466. [redacted] } (PX2306 (Illumina) at 008-021 [redacted] (*in camera*)).

4467. {[redacted]} (PX8396 (Roche/FMI) [redacted] (*in camera*)).

4468. Guardant's Mr. Getty testified that he has multiple concerns with the supply agreement, including lack of insight into Grail's prices (which are used as a ceiling for Guardant's prices), inability to monitor whether Guardant is getting new technology from Illumina at the same time as Grail, and lack of an enforceable firewall. (PX7040 (Getty (Guardant)

IHT at 183-89)). Mr. Getty further testified that, although certain provisions of the supply agreement may be helpful to Guardant, "it doesn't change the underlying premise of our analysis that the combined company would have the opportunity and incentives to advantage Grail in a competitive environment." (Getty (Guardant) Tr. 2561).

4469. [redacted] (PX7105 (Getty (Guardant) Dep. at 77) (*in camera*)).

4470. {[redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 117-18) (*in camera*)).

4471. [redacted]} (PX7068 (Perettie (FMI-Roche) IHT at 97-98; 101; 103-04; 110) (*in camera*)).

4472. [redacted] (PX7111 (Fesko (Natera) Dep. at 98) (*in camera*)).

4473. [redacted] (Rabinowitz (Natera) Tr. 368-72) (*in camera*)).

(1) [redacted]}

4474. [redacted]} (PX8383 (Tempus) [redacted] (*in camera*)).

4475. Tempus is a precision medical company headquartered in Chicago, Illinois that currently offers diagnostic tests and data services, including its xF and xT therapy selection tests. (PX7080 (Silvis (Tempus) Dep. at 16-17, 26, 29-30).

4476. [redacted] (PX7080 (Silvis (Tempus) Dep. at 49-50, 65-66) (*in camera*)).

4477. [redacted] (PX7080 (Silvis (Tempus) Dep. at 48-49, 51-52) (*in camera*)).

4478. [redacted] (PX8383 (Tempus) (*in camera*)); PX2306 (Illumina) at 008-021 (*in camera*)); PX8396 (Roche/FMI) (*in camera*)).

f) Illumina's March 2021 Open Offer Letter

4479. After engaging in supply agreement negotiations with customers and hearing concerns about the acquisition from oncology customers, Illumina made public a standardized twelve-year supply agreement referred to as an "Open Offer" on its website. (Berry (Illumina) Tr. 687-89; PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

4480. The Open Offer listed on Illumina's website is dated March 29th, 2021. (Berry (Illumina) Tr. 690; PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

4481. The Open Offer contains standardized 12-year supply agreement terms for Illumina's oncology customers. (Berry (Illumina) Tr. 688, 690).

4482. Ms. Berry is Illumina's signatory on the Open Offer. (Berry (Illumina) Tr. 690; PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

4483. On September 8, 2021, in the middle of trial, Illumina published a revised open offer letter (RX3935 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

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

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4489. Mr. Getty of Guardant testified that Guardant is "inextricably tied to Illumina in order to be successful or to run our lab," including through the supply of critical instruments and reagents, servicing of the technology, and optimization of the products to Guardant's tests. (PX7105 (Getty (Guardant) Dep. at 55-56)).

4490. Mr. Getty further testified, "the Illumina logo could be placed on the lab." (PX7105 (Getty (Guardant) Dep. at 56)).

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b) Illumina's Commitment to Product Services Is Flawed

4495. The Open Offer states that a "[c]ustomer shall have access to the same product services and support services for purchase relating to the Supplied Products to which GRAIL or any For-Profit Entity has access, or which Customer had access before the Transaction." (PX0064 § 4.a. (Illumina, Open Offer Letter, Mar. 29, 2021)).

4496. The Open Offer does not define "product services" or "support services." (PX0064 § 4.a. (Illumina, Open Offer Letter, Mar. 29, 2021)).

4497. The Open Offer does not explain how such services could be measured to ensure consistency in treatment between Grail and its rivals. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

4498. Nowhere in the Open Offer is the term "access" defined. (*See* PX0064 (Illumina, Open Offer Letter, Mar. 29, 2021)).

4499. Illumina's own executive and Open Offer signatory, Nicole Berry, testified that customers would not know how fast its competitors receive service and support from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)); *see also* PX7105 (Getty (Guardant) Dep. at 69-71) (testifying that Illumina could "say simple things like '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.")).

4500. [redacted] (deSouza (Illumina) Tr. 2440-41; *see* PX7085 (Harada (Exact) Dep. at 187-88 (*in camera*)) [redacted]).

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4505. Ms. Berry testified that under the Open Offer, a customer would not know in real-time how fast its competitors receive service and support from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)).

4506. Mr. George, Invitae's CEO, testified that under Open Offer term 4(a) it is "not clear" how Invitae will know they are receiving access to the same product services and support services as GRAIL. (PX7081 (George (Invitae) Dep. at 93-94)).

4507. Mr. Getty testified that Illumina's control over which MCED test developer receives better treatment makes it "very difficult" to audit how equitable Illumina's customer service is: "[T]he individual that was chosen to go to Guardant Health could simply have had a vacation scheduled so that seems like normal course of business. But the person who didn't have a vacation scheduled ended up at GRAIL. . . So even a third party auditor would be – it would be very difficult to gauge like for like in terms of services." (PX7105 (Getty (Guardant) Dep. at 85-86)).

4508. Respondents' Expert, Ms. Guerin-Calvert, testified that an Illumina customer would not know how fast its competitors received service and support from Illumina. (RX6002 (Guerin-Calvert Trial Dep. at 151)).

4509. Ms. Guerin-Calvert agreed that Illumina's customers have different service contracts and different service needs. (RX6002 (Guerin-Calvert Trial Dep. at 151-52)).

4510. Ms. Guerin-Calvert agreed that an Illumina customer is not well positioned to compare the services it receives from Illumina with the services that its competitor receives. (RX6002 (Guerin-Calvert Trial Dep. at 152)).

(1) MCED Customers Rely on Illumina Product and Support Service

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4522. Guardant relies on Illumina in its development and the fine-tuning of Guardant's technology. (Getty (Guardant) Tr. 2509, 2514).

4523. Guardant relies upon Illumina to service its sequencers. (Getty (Guardant) Tr. 2509).

4524. Illumina technicians come to Guardant's lab to work on sequencers on a regular basis, probably weekly. (Getty (Guardant) Tr. 2514).

4525. 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).

4526. Illumina updates its sequencers' software from time to time. (deSouza (Illumina) Tr. 2383).

c) Illumina's Commitment to Supplied Products Is Flawed

4527. The Open Offer states that a "[c]ustomer shall have access to the Supplied Products for purchase that GRAIL or any For-Profit Entity has access within 45 days of when GRAIL or such For-Profit Entity, as applicable, is offered such access (if not earlier) for purchase." (PX0064 at 006 (Illumina Open Offer Letter, Mar. 29, 2021)).

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(1) Illumina Can Customize Its Consumables to Favor Grail

4536. [redacted]} (*See* deSouza (Illumina) Tr. 2434 (testifying that Illumina can design products that "take into account modifications that will improve GRAIL's work flow"); [redacted]}.

4537. [redacted] Illumina has previously collaborated with Grail on "extraction methodology to improve library yields" as well as collaborated with Grail on the development of library prep and sequencing kits. Some of these kits were "built specifically for GRAIL". (PX2541 (Illumina) at 010, 017 (Interim Review K2-GRAIL, Feb. 2, 2017)).

4538. [redacted]

4539. [redacted]

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(2) Supply Shortage

4541. Ms. Guerin-Calvert agreed that Illumina's MCED customers may need different levels of supply of either sequencers or consumables. (RX6002 (Guerin-Calvert Trial Dep. at 154)).

4542. Ms. Guerin-Calvert testified that she had not seen any documents or testimony that spells out how Illumina intends to allocate short supply among its customers. (RX6002 (Guerin-Calvert Trial Dep. at 154-55)).

4543. [redacted] (PX7085 (Harada (Exact) Dep. at 277-78) (*in camera*)).

(3) Illumina's Open Offer Does Not Cover Library Preparation Kits—"The Secret Sauce" of MCED Tests

4544. Illumina's library prep kits "can be customized" and that helps customers select and enrich specific targets within genetic material for sequencing. (PX7076 (Berry (Illumina) Dep. at 164-65)).

4545. [redacted] (PX7076 (Berry (Illumina) Dep. at 166-67) (*in camera*) ({ [redacted] })).

4546. { [redacted] } (PX7076 (Berry (Illumina) Dep. at 166-67) (*in camera*); deSouza (Illumina) Tr. 2456).

4547. At trial, Ms. Berry described library preparation as "the very important differential piece of the work flow between" Galleri's test and Guardant's test. (Berry (Illumina) Tr. at 679).

4548. Library preparation is "the secret sauce for each customer" and "where the IP resides" for Galleri, Guardant, Natera, or "pick your oncology testing provider." (Berry (Illumina) Tr. 679).

4549. Ms. Berry explained, "in the case of an oncology screening assay, the library preparation method would interrogate certain places in the genome that might be indicative of the presence of a potential cancer in that person." (Berry (Illumina) Tr. 820).

4550. Ms. Berry testified that there are many companies that provide library prep technology, but noted that "in order to run a library on an Illumina platform there are specific steps at the very tail end of that process that . . . make that sample compatible to be read on an Illumina sequencer." (Berry (Illumina) Tr. 816).

4551. Illumina's Open Offer refers to "Supplied Product(s)," "Pre-Release Sequencing Product," "NGS Consumables," and "Sequencing Consumables." (PX0064 at 004, 012 (Illumina Open Offer agreement, Mar. 29, 2021)).

4552. The definition of "Supplied Products" includes Illumina's NGS instruments, as well as Illumina's "Sequencing Consumables." The term "Sequencing Consumables" includes "core consumables," but it does not include library prep kits or library prep consumables." (PX0064 at 004-005 (Illumina Open Offer agreement, Mar. 29, 2021)). [redacted] } (PX7076 (Berry (Illumina) Dep. at 74) (*in camera*)).

4553. The provisions in the Open Offer that relate to customer access to supplied products and customer pricing do not include access to or pricing of library prep consumables. (PX0064 at 005-008 (Illumina Open Offer agreement, Mar. 29, 2021)).

4554. [redacted] (PX8390 (Exact) at 010-11 (Email from S. Coward, Exact, to A. Welland et al., Illumina, Jan. 19, 2021) (*in camera*) {[redacted]}).

d) Illumina's Commitment to Pre-Released Sequencing Products Is Flawed

4555. The Open Offer states that a "[c]ustomer shall have access for purchase to any Pre-Release Sequencing Product to which GRAIL or any For-Profit Entity is offered access within 45 days of when GRAIL or such For-Profit Entity, as applicable, is offered such access (if not earlier), and for the same categories of uses, specifically: (i) feedback to Illumina for development of NGS products, including through alpha or beta testing; (ii) for clinical trials; (iii) for clinical validation; (iv) for pre-commercial test development not relating to clinical trials; or (v) for a commercialized product developed by Customer. Customer's purchase of any Pre-Release Sequencing Product is subject to the pricing terms in Section 5 in this Supply Agreement. This provision does not apply to Pre-Release Sequencing Products that are developed by Illumina for a specific For-Profit Entity pursuant to a development agreement under 4.d. with such For-Profit Entity." (PX0064 at 004 (Illumina Open Offer Letter, Mar. 29, 2021)).

4556. [redacted]

4557. [redacted]

4558. Ms. Berry testified that Illumina's customers would not know whether they have access to prerelease products at the same time as Grail "unless Illumina proactively communicated such." (Berry (Illumina) Tr. 701).

4559. As Dr. Bert Vogelstein explained in his declaration, "advanced knowledge of future product developments and refinements . . . could alter the research and development of new or modified tests for the earlier detection of cancer. For example, if researchers become aware that a new sequencer or product improvements would enable the field to analyze many more genes in one test than it can do now, researchers could use that information to begin developing tests that would be more accurate and, perhaps less expensive, to perform." (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 9)).

(1) Illumina Has Already Treated Grail Preferentially with Regard to Early Access to Products

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(2) Illumina's Commitment to Providing Customers Access for Purchase to Any Pre-Release Sequencing Product Within 45 Days of When Illumina Offers the Same Pre-Release Sequencing Product to Grail Fails to Adequately Protect Customers

4566. Section 4(c) of the open offer provides that customers shall have access for purchase to any pre-release sequencing product within 45 days of when Illumina offers the same pre-release sequencing product to Grail. (Berry (Illumina) Tr. 702). Illumina's revised Open Offer shortens this time period to five days. (RX3935 at 001-002 (Illumina, Revised Open Offer Letter, Sept. 8, 2021).

4567. Illumina does not commit in the open offer to provide customers access for purchase to any pre-release sequencing products in less than the 45 days (or 5 days under the Revised Open Offer) of when Illumina offers the pre-release sequencing product to Grail. (Berry (Illumina) Tr. 703-04; RX3935 at 001 (Illumina, Revised Open Offer Letter, Sept. 8, 2021)).

4568. Illumina does not commit in the open offer to provide customers access for purchase to any pre-release sequencing products at the same time that Illumina offers the pre-release sequencing product to Grail. (Berry (Illumina) Tr. 705-06).

4569. Illumina's "ability to provide equitable access [to its products] has practical . . . limitations." (Berry (Illumina) Tr. 704-05).

4570. The open offer does not define the term "access" used in Section 4(c). (Berry (Illumina) Tr. 707).

4571. Ms. Berry testified at trial 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).

4572. Under the open offer, Grail can learn the specifications of new Illumina sequencers before its rival MCED test developers. (Berry (Illumina) Tr. 708).

4573. Guardant's William Getty testified, 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." (PX7105 (Getty (Guardant) Dep. at 69-71)).

4574. Mr. Getty testified that under the Open Offer there is no way for Guardant to know when the 45-day clock begins in which Guardant should have access to the same products as Grail. (PX7105 (Getty (Guardant) Dep. at 87)).

4575. Further, Mr. Getty testified that even if there was the ability to know when the 45-day clock begins, "it would be largely unimportant because ultimately" it would be too late. (PX7105 (Getty (Guardant) Dep. at 87-88) ("Q. Is there any way for Guardant to known when that – the 45-day clock begins in which Guardant should have access to the same products as GRAIL? A. No. And even if there was an ability to do so, it would be largely unimportant because ultimately, you know, if we go back to the example of a product being developed and, you know, the interaction of a test with that product, product being, say, a sequencer, imagine a scenario where the, you know, head of GRAIL's research and development speaks with the heads of Illumina's sequencer development, the head of Illumina's sequencer development says, you know, "Ultimately we will have this technology available on" such and such date. And GRAIL's R&D engine is able to ramp up quickly in order to take advantage of that technological advance much faster than the competitive set. So, you know, whether or not we have even an ability to see it, which we wouldn't, ultimately there's also additional impacts that would be negative to Guardant, relatively speaking, from the combined company.")).

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(a) Ms. Guerin-Calvert's Pre-Release Products Analysis Does Not Meet Her Own Report's Standards

4587. Ms. Guerin-Calvert's expert report does not analyze whether Grail can access information about Illumina's pre-release products before Grail's competitors. (RX6002 (Guerin-Calvert Trial Dep. at 147)).

4588. Ms. Guerin-Calvert testified that if Illumina gave Grail a pre-release product without requiring that Grail purchase the product that such an arrangement would be equivalent to a zero-price transfer. (RX6002 (Guerin-Calvert Trial Dep. at 147-48)).

4589. Ms. Guerin-Calvert testified that a zero-price transfer could potentially trigger Section 5(f) of the Illumina open offer. (RX6002 (Guerin-Calvert Trial Dep. at 148)).

4590. Ms. Guerin-Calvert testified that she is not providing an opinion as to whether an arbitrator must find that giving GRAIL access to a pre-release sequencing product without purchasing it is a zero-price transfer. (RX6002 (Guerin-Calvert Trial Dep. at 148)).

4591. Ms. Guerin-Calvert testified that she is not providing an opinion as to whether an arbitrator must find that such a transfer of a pre-release Illumina sequencing product triggers Section 5(f) of the open offer. (RX6002 (Guerin-Calvert Trial Dep. at 148)).

4592. Ms. Guerin-Calvert did not evaluate any potential lost revenues an MCED test developer would suffer as a result of a delay in accessing a pre-release product from Illumina. (RX6002 (Guerin-Calvert Trial Dep. at 149-50)).

4593. Ms. Guerin-Calvert did not evaluate any loss to an MCED test developer's gross profits as a result of a delay in accessing a pre-release product from Illumina. (RX6002 (Guerin-Calvert Trial Dep. at 150)).

(3) Early Access to New Products

4594. [redacted] (*See* PX0064 (Illumina Open Offer agreement, Mar. 29, 2021); *see also* PX7068 (Perettie (FMI-Roche) IHT at 99-100) (*in camera*)).

4595. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 100) (*in camera*)).

4596. The last clause in the Open Offer "Access to Pre-Release Sequencing Products" term states, "This provision does not apply to Pre-Release Sequencing Products that are developed by Illumina for a specific For-Profit Entity pursuant to a development agreement under 4.d. with such For-Profit Entity." (PX0064 at 007 (Illumina Open Offer agreement, Mar. 29, 2021)).

4597. [redacted] (PX7068 (Perettie (FMI-Roche) IHT at 100-01) (*in camera*)).

4598. One of Mr. Getty's concerns about the Proposed Acquisition is that sharing information about a new sequencer in development could give Grail a "significant head start" on developing the next version of its assay. (Getty (Guardant) Tr. 2518-19).

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4605. [redacted]

4606. [redacted]

4607. Dr. Vogelstein testified that based on his "knowledge and experience as a cancer researcher" the "advanced knowledge of future product developments and refinements from Illumina's public announcements could alter the research and development of new or modified tests for the earlier detection of cancer." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 69-71)). As an example, Dr. Vogelstein testified that "if researchers become aware that a new sequencer or product improvements" have been made then this "would enable the field to analyze many more genes in one test than it can do now" and "researchers could use that information to begin developing tests that would be more accurate and perhaps less expensive to perform." (PX7101 (Vogelstein (JHU Johns Hopkins University Dep. at 70-71)).

4608. Dr. Vogelstein testified that the "foreknowledge" about future product developments and refinements of Illumina's products "could substantially alter research and development in the field and the nature of the test products that are eventually produced." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 70)).

e) Illumina's Development Agreement Commitment Is Flawed

4609. The Open Offer states that a "Illumina shall enter into, upon Customer request, a separate development agreement with Customer on commercially reasonable terms, relating to the design or modification of any Supplied Product, in a manner that optimizes interoperability with Customer's tests, including, without limitation, capabilities, performance, speed, efficiency, cost, convenience, accuracy, specificity, precision, ease of use and user experience." (PX0064 at 006 (Illumina Open Offer agreement, Mar. 29, 2021)). Ms. Berry explained that "this provision provides the opportunity for Illumina and the customer to discuss and develop potentially a separate agreement that might relate to a customer's interest in modifying a supplied product specifically for that customer and to, you know, work optimally with that customer's part of the workflow or their tests." (Berry (Illumina) Tr. 881).

4610. Ms. Berry testified that she is not aware of any development agreements Illumina has with any of its customers. (PX7076 (Berry (Illumina) Dep. at 280)).

4611. [redacted]

4612. [redacted]

4613. [redacted]

4614. [redacted]

4615. Dr. Scott Morton, testified that "[u]nder the status quo" meaning if Illumina and Grail remain separate "Illumina has an incentive to help its customers develop profitable products so that it can sell sequencing. It will be helping those consumers in any way that makes sense that enables [Illumina] to increase its sales and without owning GRAIL, [Illumina] has that incentive for all MCED developers." (RX3852 (Scott Morton Dep. at 256)).

4616. Ms. Scott Morton continued to explain that if Illumina and Grail remain separate, customers will not need a development agreement guarantee from Illumina because Illumina will have an incentive to work with the customer. "If there is no reason to enter into the development agreement because Illumina wouldn't make money, Illumina won't. But if [Illumina] will [make money], then they have an incentive to do it, and that protects those customers." (RX3852 (Scott Morton Dep. at 256)).

4617. Prior to Illumina and Grail closing their transaction, customers did not have a commitment from Illumina to enter into a development agreement. However customers did not "need one because the competition protects them. Illumina doesn't own GRAIL and doesn't have an incentive to foreclose against them." (RX3852 (Scott Morton Dep. at 256-57)).

f) Illumina's No Obsolescence Commitment Is Flawed

4618. The Open Offer states that "Illumina shall not discontinue any Supplied Product so long as Customer continues to purchase that Supplied Product. Illumina may discontinue a Supplied Product that Customer has not purchased in more than one year." (PX0064 at 006 (Illumina Open Offer agreement, Mar. 29, 2021)).

4619. [redacted]

4620. [redacted]

[redacted]

4621. [redacted]

4622. [redacted]

4623. [redacted]

4624. [redacted]

4625. [redacted]

[redacted]

4626. [redacted]

4627. [redacted]

4628. [redacted]

4629. [redacted]

4630. [redacted]
(RX6002 (Guerin-Calvert Trial Dep. at 151) (*in camera*)).

g) Illumina's Pricing Commitments Are Flawed

4631. Mr. deSouza testified the Open Offer provides that a customer "will get access to the same prices" as Grail. (deSouza (Illumina) Tr. 2402).

4632. Specifically, the Open Offer provides that Illumina will not increase prices, and that, by 2025, the volume-based price "per gigabase of sequencing using the highest throughput Illumina instrument then available . . . will be at least 43% lower" than the current price per gigabase of sequencing using the NovaSeq instrument. (PX0064 (Illumina) at 007 (Open Offer § 5d New Product Pricing, Mar. 29, 2021)).

4633. [redacted]

4634. Because the Open Offer states that a customer will get access to the same prices as Grail, this means that Illumina has to provide its products to Grail's rivals at cost—something that Respondents have never alleged, and that Carlton admits "is not my understanding." (RX6000 (Carlton Trial Dep. at 142)).

4635. [redacted]

4636. [redacted]

4637. [redacted]

4638. Helio's CEO, Mr. Chahine, testified that post acquisition "Illumina would be Grail, so I don't know what giving Grail a price actually means in this context." (PX7077 (Chahine (Helio) Dep. at 114-15)).

(1) Pricing Terms Allow for Illumina Manipulation

4639. Illumina can offer customers discretionary discounts off of the public pricing discount grid for special projects or to upgrade sequencers. (deSouza (Illumina) Tr. 2440-43; *see* PX6056 (Illumina) at 022 (Narrative Response to Second Request, Mar. 1, 2021 ("Illumina from time to time negotiates customer-specific discounts" and "promotional discounts")).

4640. Illumina's does not publish other oncology customers' discretionary discounts. (deSouza (Illumina) Tr. 2440).

4641. [redacted] (Berry (Illumina) Tr. 781 (*in camera*)).

4642. Under the Open Offer, customers are only eligible to receive discretionary discounts for activities that are considered "short term projects" as defined in the Open Offer, meaning the activities fall outside of the normal course of business. (Berry (Illumina) Tr. 925; PX0064 at 008 (Illumina Open Offer agreement, dated March 30, 2021)).

4643. Ms. Berry testified that discretionary discounts determine the "ultimate[] price the customer pays." (PX7063 (Berry (Illumina) IHT at 17-18)).

4644. Some of Illumina's customers have negotiated lower pricing than what is contemplated in the Open Offer. (Berry (Illumina) Tr. 926).

4645. [redacted]

4646. Transactions between Illumina and Grail are now between two Illumina entities. (deSouza (Illumina) Tr. 2462).

4647. Illumina will be responsible for publishing any prices on Grail's website. (deSouza (Illumina) Tr. 2466).

4648. The price at which Grail purchases products from Illumina represents the price at which one Illumina entity purchases from another. (deSouza (Illumina) Tr. 2465).

4649. The price Illumina charges to its Grail subsidiary for consumables will have no net impact on the combined entity's net P&L. (deSouza (Illumina) Tr. 2467-68).

4650. The price Illumina charges to its Grail subsidiary for sequencers will have no net impact on the combined entity's net P&L. (deSouza (Illumina) Tr. 2469-70).

4651. Grail's own Vice President of Finance, Aaron Freidin, testified that while he does not know how Illumina will account for Grail's purchases of Illumina products, he does know "that it's all eliminates and you end up with a true cost at the end when you report your financials as a public company." (Freidin (Grail) Tr. 3153).

4652. Respondents' economic expert, Dr. Carlton, likewise testified that "GRAIL doesn't technically pay a price. If you want to make up a scenario in which you force GRAIL to 'pay some price,' and you call that a transfer price . . . I'm happy to make that assumption." (RX6000 (Carlton Trial Dep. at 141-42)).

4653. Section 5(d) of the Open Offer provides that the price per giga base of sequencing on Illumina's then-available highest throughput instrument will be 43 percent lower than the price per giga base of sequencing using the NovaSeq sequencer. (Berry (Illumina) Tr. 710-11).

4654. The Open Offer only provides for a 43 percent price decrease on Illumina's highest throughput instrument. (Berry (Illumina) Tr. 712; PX0064 at 005 (Illumina Open Offer, Mar. 29, 2021)).

4655. Under Section 5(d) of the Open Offer, if Illumina introduces a higher throughput instrument than the NovaSeq by 2025, the 43 percent price decrease commitment would only apply to that new, higher throughput sequencer. (Berry (Illumina) Tr. 712).

4656. Ms. Berry testified at trial that customers that are currently developing multicancer early detection tests on the NovaSeq would have to switch to the new higher throughput instrument in order to benefit from the pricing decrease. (Berry (Illumina) Tr. 713).

4657. The Open Offer provides no guarantee that Illumina will reduce the price of its sequencers before 2025. (Berry (Illumina) Tr. 714-15).

4658. The Open Offer provides Illumina's MCED test developing customers with no guarantee that Illumina will reduce the price of its sequencers by more than 43 percent by 2025. (Berry (Illumina) Tr. 715).

4659. It costs approximately $600 to sequence one person's genome today. (Berry (Illumina) Tr. 716).

4660. Illumina has publicly announced its intent to drive sequencing costs down to $100 per genome. (Berry (Illumina) Tr. 715).

4661. Illumina anticipates that sequencing costs will fall significantly over time. (PX7104 (Aravanis (Illumina) Dep. at 219-220)).

4662. Ms. Berry testified at trial that a sequencing cost decrease from $600 to $100 is more than the 43 percent price decrease in Illumina's open offer. (Berry (Illumina) Tr. 715 (a decrease from $600 to $100 per genome would be a 83 percent decrease)).

4663. Ms. Berry testified that a $100 genome is a stated goal of Illumina's. (Berry (Illumina) Tr. 715).

4664. Ms. Berry confirmed that the Open Offer does not guarantee a reduce in Illumina's pricing more than 43 percent. (Berry (Illumina) Tr. 715).

4665. Ms. Berry testified that Illumina's sequencing cost for one genome on the NovaSeq 6000 is about $600. (Berry (Illumina) Tr. 716).

4666. Ms. Berry testified that a price decrease from $600 to $100 is much more than a 43 percent price decrease. (Berry (Illumina) Tr. 716).

4667. Illumina's CEO, Mr. deSouza testified that today Illumina is already at a $600 genome and Illumina has "publicly said we are going to take it down by another 80 percent, [to] $100 a genome." (deSouza (Illumina) Tr. 2398).

4668. [redacted]

4669. [redacted] (PX2558 (Illumina) at 012 (Email from E. Milsovic, Illumina, to F. deSouza, Illumina, attaching February 2021 Board of Directors Executive Session Presentation, Feb. 9, 2021) (*in camera*)).

4670. [redacted]

4671. [redacted]

[redacted]

4672. {[redacted]

4673. [redacted] (PX7138 (Scott Morton Trial Dep. at 76) (*in camera*)).

4674. [redacted]} (PX7138 (Scott Morton Trial Dep. at 76-77) (*in camera*)).

(2) Illumina's 43% Per Gigabase of Sequencing Price Reduction on Sequencing Products by 2025 Compared to Moore's Law

4675. Section 5(d) of the Open Offer only commits to a 43 [] percent price decrease for price per giga base of the then-available highest throughput instrument. (Berry (Illumina) Tr. 923; PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021)).

4676. The 43 percent price decrease only relates to the price per gigabase of the sequencing rather than the price per read. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 923)).

4677. The Open Offer indicates that customers will receive a 43% decrease in sequencing costs per giga base by 2025, enabled by the anticipated improvements in Illumina's sequencing technology. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021)).

4678. Illumina's Open Offer commits to a 43 percent reduction in the cost per giga base for the then-available highest throughput instrument that Illumina sells. (Berry (Illumina) Tr. 923).

4679. Ms. Berry explained that "per giga base of sequencing" was used because "sequencing flow cells are described in terms of capacity in a number of gig abases able to be sequenced. So if we describe pricing in a price-per-gigabase nomenclature, it allows us essentially to normalize the different capacity flow cells and compare different kits' pricing on sort of an

apples-to-apples basis. So it would be analogous to, say, price per gallon if you're looking at, you know, say, milk purchased in a gallon container versus in a tractor-trailer truckload. So it's simply a way for us to conveniently refer to a normalized price that allows us to easily understand whether or not, relative to or irrespective of quantity or capacity in this case of a flow cell, whether or not the price is actually higher or lower." (Berry (Illumina) Tr. 904-05).

4680. [redacted]

4681. [redacted]

4682. [redacted]

[redacted]

4683. [redacted]

4684. [redacted]

4685. [redacted]

4686. [redacted]

4687. [redacted]

4688. [redacted]

4689. [redacted]

4690. [redacted]

4691. [redacted]

4692. [redacted]

4693. [redacted]

[redacted]

[redacted]

4694. [redacted]

4695. [redacted]

4696. Ms. Berry testified that if Illumina does introduce an instrument with a higher throughput than the NovaSeq, currently Illumina's highest throughput instrument, then the 43 percent price decrease would only apply to that new, higher throughput sequencer. (Berry (Illumina) Tr. 712).

4697. If Illumina introduced an instrument with throughput higher than the NovaSeq, Ms. Berry confirmed that customers that are currently developing multicancer early detection tests on the NovaSeq would have to switch to the new higher throughput instrument in order to benefit from the pricing decrease. (Berry (Illumina) Tr. 713).

4698. Section 5(d) of the Open Offer provides a 43 percent pricing decrease by 2025, however, it is not specified in the Open Offer whether that is January 1, 2025 or December 31, 2025. (PX0064 at 007 (Illumina Open Offer, Mar. 29, 2021); Berry (Illumina) Tr. 713-14).

4699. Flatley's law, named after Illumina's prior CEO Jay Flatley, is the comparison between sequencing pricing and Moore's law. (Berry (Illumina) Tr. 811).

4700. Ms. Berry testified that "'Flatley's law' was a term coined by an author – a writer in Forbes magazine when he wrote an article comparing the reduction in the price of sequencing to Moore's law, which describes the reduction in the price of like silicon wafers or something in the computer industry, and specifically under Jay Flatley, our former CEO's leadership, and it was during, you know, his leadership where we really drove significant, significant reductions in the price of sequencing, you know, down towards the level that they are today. And you know, "Moore's law" was the – was the term that describes the reduction in price in the silicon wafer, and "Flatley's law" then was coined to describe the dramatic reduction in price in genomics that has – that was achieved during Jay Flatley's leadership of Illumina." (Berry (Illumina) Tr. 811).

4701. Dr. Aravanis testified that Illumina has "longer-term goals" to bring down the cost of sequencing more than the 43 percent stated in the Open Offer. (Aravanis (Illumina) Tr. 1868).

4702. Dr. Vogelstein testified that Illumina's NGS sequencing costs have "gone down considerably" over time and "they call it analogous to computers." (PX7101 (Vogelstein (Johns Hopkins University) Dep. at 62)).

4703. [redacted]

(a) Ms. Guerin-Calvert's Price Per Gigabase and Equivalent Pricing Analysis Does Not Meet Her Own Report's Standards

4704. When analyzing Illumina's grandfathered versus universal pricing, Respondent's Expert, Ms. Guerin-Calvert used price per gigabase as a comparator because "[p]rice per gigabase is a standard metric that is used that makes for -- the possibility for comparing across various products. It's a standard way of doing it, and that was my basis for using it." (RX6002 (Guerin-Calvert Trial Dep. at 43)).

4705. Ms. Guerin-Calvert testified that an MCED test developer would have to rely on Illumina's assurances that the customer received equivalent pricing as Grail. (RX6002 (Guerin-Calvert Trial Dep. at 144).

4706. [redacted] (RX6002 (Guerin-Calvert Trial Dep. at 144-45).

h) Illumina's FDA Commitments Are Flawed

4707. The Open Offer states that "Customer may enter into, at any time from today, effective as of the closing of the Transaction, until the sixth anniversary of the closing of the Transaction, an agreement with Illumina under which Customer may develop and commercialize in-vitro diagnostic ("IVD") test kits for use on Illumina's diagnostic ("Dx") sequencing platforms. Illumina will provide standard terms for Customer to enter into a standalone agreement to enable Customer to develop and commercialize IVD test kits on one or all of Illumina's Dx sequencing platforms. Illumina shall provide any documentation or information reasonably required for Customer to seek FDA approval or FDA marketing authorization to sell a for-profit, clinical test using the Supplied Products." (PX0064 (Illumina) at 006-7 (Illumina Open Offer, Mar. 29, 2021)).

4708. [redacted]

4709. [redacted]

4710. [redacted]

4711. {[redacted]

(1) Illumina's IVD Agreement Requires Technology Access Fees, Milestone Payments, and Royalty Fees for Customers to Have an FDA Cleared Distributed Test Product

4712. [redacted]} (PX7120 (Young (Illumina) Dep. at 8) (*in camera*)).

4713. [redacted]} (PX7120 (Young (Illumina) Dep. at 9-10) (*in camera*)).

4714. Illumina's Open Offer includes revenue sharing that requires its customers to pay 6% of net IVD sales to Illumina. (PX0064 at 029-030 (Illumina Open Offer, Mar. 29, 2021)).

4715. If a customer wanted a different revenue share percentage with Illumina than 6%, the customer would need to negotiate with Illumina. (Goswami (Illumina) Tr. 3269).

i) Illumina's Intellectual Property Commitments Are Flawed

4716. The Open Offer's IP provisions at section 9 address two categories of IP: "Core IP Rights" and "IP Infringement." (PX0064 at 009 (Illumina Open Offer agreement, Mar. 29, 2021)).

4717. The Open Offer's Core IP Rights provision states: "Customer's purchase of Supplied Products under this Supply Agreement confers upon Customer the non-exclusive, non-transferable, personal, non-sublicensable right solely under Illumina's Core IP to use the Supplied Products, only with Illumina hardware and software, and only in Customer facilities. Except as expressly stated in this Section 9 with respect to Core IP, no right or license under any Illumina Intellectual Property Rights is granted, expressly, by implication, or by estoppel, to Customer under this Supply Agreement." (PX0064 at 009 (Illumina Open Offer agreement, Mar. 29, 2021)).

4718. The Open Offer's IP Infringement provision states: "In no event will Illumina have the right to cease shipping of the Supplied Product solely on the basis of any alleged claim of infringement of any intellectual property rights of Illumina." (PX0064 at 009 (Illumina Open Offer agreement, Mar. 29, 2021)).

4719. Illumina's Open Offer provides no prohibition against Illumina suing the customer for IP infringement and does not provide for a customer to license any application specific IP. (*See* PX0064 at 003-004, 009, 039 (Illumina Open Offer agreement, Mar. 29, 2021)).

4720. [redacted]

4721. [redacted]

4722. [redacted]

4723. [redacted]

j) Illumina's Commitments to Confidentiality Are Flawed

4724. [redacted]

4725. [redacted]

4726. [redacted]

4727. [redacted]

(1) The Open Offer's Firewall Provision Is Insufficient to Prevent Sharing of Competitively Sensitive Information Between Grail and Illumina

4728. The Open Offer provides that "Illumina shall establish a firewall designed to prevent any GRAIL personnel (and any Illumina personnel carrying out activities with respect to the GRAIL business or products) from accessing any Confidential Information obtained by or made available to Illumina relating to Customer or its business or products, whether

pursuant to this Supply Agreement or otherwise." (PX0064 at 009-010 (Illumina Open Offer agreement, Mar. 29, 2021)).

4729. [redacted]

4730. [redacted]

4731. [redacted]

4732. Guardant's Mr. Getty testified that Illumina's firewall provision does "not at all" alleviate Guardant's concerns about the sharing of competitively sensitive information with Illumina. (PX7040 (Getty (Guardant) IHT at 188)).

4733. Mr. Getty testified that "individuals on [Illumina's] executive team have traded back and forth already. . . . There are individuals – you know, Illumina was an early investor in Grail, and there are individuals who are on the executive team at Illumina who hold large stakes in Grail." (PX7040 (Getty (Guardant) IHT at 188-89)).

4734. Mr. Getty of Guardant testified that it is difficult for Guardant to know whether someone from Illumina's sequencing business has spoken with someone in Grail's business. (PX7105 (Getty (Guardant) Dep. at 79-80)).

4735. Mr. Getty testified with respect to Guardant's concerns about its confidential information being shared between Illumina and Grail, "Illumina has an incentive to share that information with GRAIL." (PX7105 (Getty (Guardant) Dep. at 100)).

4736. Mr. Getty testified, "presumably a combined company, the head of GRAIL and the head of Illumina, you know, at all different levels, head of, you know, R&D, head of commercial, head of, you know, operations, what have you, all those individuals would be shareholders in a combined company. And so certainly they all play – have a financial and perhaps even other incentives to share information and create the most competitive GRAIL that can possibly exist in order to win the 60-billion-dollar market." (PX7105 (Getty (Guardant) Dep. at 100-01)).

4737. When asked what specifically was flawed about Illumina's firewall provision, Mr. Getty testified: "There's no enforceability of it. And with – if it was breached, how would [Guardant] know, right." (PX7040 (Getty (Guardant) IHT at 189)).

4738. Mr. Getty testified that with a combined Illumina-Grail, "you have now a circumstance where incentives are in-lined to share information to create a more competitive GRAIL organization. And so ultimately what you will see persist, of course, is exactly that, the sharing of that information." (PX7105 (Getty (Guardant) Dep. at 101)).

4739. Mr. Getty testified that pre-acquisition, "while Illumina [had] all that information, there [was] less of an incentive to share that with [Guardant's] competitors, right, because ultimately [Illumina] would – they would be doing something that really wouldn't convey benefit for anybody and maybe create a negative environment." (PX7105 (Getty (Guardant) Dep. at 101)).

4740. When asked whether the firewall provision in the Open Offer alleviates concerns about sharing of competitively sensitive information, Mr. Getty testified, "No, it does not. I – you know, I think the notion of a firewall invokes something that is impossible to enforce." (PX7105 (Getty (Guardant) Dep. at 102)).

4741. Mr. Getty testified that "there are many examples, particularly in the banking industry, where firewalls have proven to be nothing of the sort. And, you know, it's also nearly impossible to actually enforce, relatively speaking, if, you know, you're not – yeah. It's just – it's not enforceable." (PX7105 (Getty (Guardant) Dep. 102)).

4742. [redacted]

4743. [redacted]

4744. [redacted]

4745. [redacted]

4746. [redacted]

4747. [redacted]

[redacted]

4748. Ms. Berry testified at trial that the Open Offer does not define what constitutes "Confidential Information." (Berry (Illumina) Tr. 716-18).

4749. [redacted]

4750. [redacted]

4751. [redacted]

4752. [redacted]

4753. [redacted]

4754. [redacted]

4755. [redacted]

4756. After Illumina closed its acquisition of Grail, Illumina added a new account manager, Linda Ray, to handle the Grail account. (Berry (Illumina) Tr. 931).

4757. Linda Ray reports to Ms. Abernathy, who reports to Curtis Fideler, who reports to Ms. Berry. (Berry (Illumina) Tr. 931-32).

4758. {[redacted]} (PX7076 (Berry (Illumina) Dep. at 78-81) (*in camera*) ({[redacted]})).

4759. [redacted] (Ofman (Grail) Tr. 3405 (*in camera*)).

4760. [redacted] (Ofman (Grail) Tr. 3406 (*in camera*)).

4761. Illumina SVP of Corporate Development and Strategic Planning, Joydeep Goswami, testified that he oversees all of Illumina's customer contracts. (Goswami (Illumina) Tr. 3229).

4762. Mr. Goswami testified, "There's generally a set of [customer-related] things that I need to know and I can get that." (Goswami (Illumina) Tr. 3229).

4763. [redacted]

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[redacted]

[redacted]

[redacted]

4782. [redacted]

(3) Respondents' Expert Ms. Guerin-Calvert's Firewall Analysis Does Not Meet Her Own Report's Standards

4783. Respondent's Expert, Ms. Guerin-Calvert's Expert Report identifies certain characteristics of an effective and enforceable firewall. (RX6002 (Guerin-Calvert Trial Dep. at 118); RX3865 (Guerin-Calvert Rebuttal Report) ¶ 97).

4784. Ms. Guerin-Calvert's first criteria for an effective and enforceable firewall in Ms. Guerin-Calvert's Expert Report is "[c]onfidentiality policies, procedures and protocols that describe the specific persons and positions that can have access to competitively sensitive information." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 97).

4785. Ms. Guerin-Calvert testified that she had not investigated which specific persons at Illumina would have access to competitively sensitive information. (RX6002 (Guerin-Calvert Trial Dep. at 118-19)).

4786. Ms. Guerin-Calvert testified that she did not know what process Illumina was using to identify individuals who would have access to competitively sensitive information. (RX6002 (Guerin-Calvert Trial Dep. at 119)).

4787. Ms. Guerin-Calvert's second criteria for an effective and enforceable firewall in Ms. Guerin-Calvert's Expert Report is "[c]lear definitions of what constitutes competitively sensitive information and thoroughly describes and captures the information that needs to be protected from dissemination." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 97).

4788. Ms. Guerin-Calvert testified that she did not know at what stage Illumina was in terms of developing its implementation plan for the audit program and the firewall. (Guerin-RX6002 (Guerin-Calvert Trial Dep. at 119-20)).

4789. Ms. Guerin-Calvert testified that she did not know what specific competitively sensitive information was to be protected through the firewall. (RX6002 (Guerin-Calvert Trial Dep. at 120)).

4790. Ms. Guerin-Calvert testified that she did not know who at Illumina was in charge of identifying the specific competitively sensitive pieces of information that would be protected by the firewall. (RX6002 (Guerin-Calvert Trial Dep. at 120-21)).

4791. Ms. Guerin-Calvert testified that she had not seen any specific implementation plans that documented how Illumina would prevent its employees with access to third-party competitively sensitive information from sharing it with Grail. (RX6002 (Guerin-Calvert Trial Dep. at 122-23)).

4792. Ms. Guerin-Calvert's fourth criteria for an effective and enforceable firewall in Ms. Guerin-Calvert's Expert Report is "[e]stablished policies and procedures for reporting of violations." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 97).

4793. Ms. Guerin-Calvert testified that she did not know who at Illumina had been designated to receive any complaints of firewall violations related to Grail. (RX6002 (Guerin-Calvert Trial Dep. at 123)).

4794. Ms. Guerin-Calvert had not seen any documents laying out the policies and procedures for reporting a violation of a firewall that might be implemented in the context of the Illumina/Grail transaction. (RX6002 (Guerin-Calvert Trial Dep. at 123)).

4795. Ms. Guerin-Calvert testified that she did not recall any specific information about Illumina's policies and procedures for reporting a violation of a firewall. (RX6002 (Guerin-Calvert Trial Dep. at 123-24)).

4796. Ms. Guerin-Calvert's fifth criteria for an effective and enforceable firewall in Ms. Guerin-Calvert's Expert Report is "[m]eaningful consequences for violation." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 97).

4797. Ms. Guerin-Calvert testified that she was neither aware of information regarding, nor could she identify specific instances, where Illumina administered a punishment or some other consequence as a result of an employee violating a confidentiality agreement. (RX6002 (Guerin-Calvert Trial Dep. at 124)).

4798. Respondent's Expert, Ms. Guerin-Calvert has never served as a compliance monitor for the antitrust agencies. (RX6002 (Guerin-Calvert Trial Dep. at 125-26)).

4799. Ms. Guerin-Calvert's Expert Report cites to six consent decrees that used firewalls. (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 99). But Ms. Guerin-Calvert did not work on any of the six matters cited to in her report. (RX6002 (Guerin-Calvert Trial Dep. at 125)).

4800. In preparing her report, Ms. Guerin-Calvert did not review any of the compliance reports filed in the six consent decrees that used firewalls. (RX6002 (Guerin-Calvert Trial Dep. at 126-27).

4801. Ms. Guerin-Calvert did not interview any of the monitors in the six consent decrees that used firewalls. (RX6002 (Guerin-Calvert Trial Dep. at 127).

4802. Ms. Guerin-Calvert testified that she does not know if there was a firewall violation in any of the six consent decrees that used firewalls. (RX6002 (Guerin-Calvert Trial Dep. at 127-28).

4803. Ms. Guerin-Calvert testified that she does not know if there were changes to the list of individuals who could receive confidential information over the life span of any the six consent decrees that used firewalls. (RX6002 (Guerin-Calvert Trial Dep. at 127-28)

k) The Open Offer Is Difficult to Monitor and Enforce

4804. Mr. Getty testified further that "a contract is only as good as it is enforceable. And ultimately, you know, our ability – our ability, being Guardant's ability . . . to investigate adherence to the term of that contract is nearly impossible." (PX7105 (Getty (Guardant) Dep. at 79-80)).

4805. Mr. Getty testified that Guardant "[doesn't] have the ability to audit. We also -- you know, in a different context, we also don't have the ability to know what goes on on a day-to-day basis at Illumina. You know, did the head of sequencing have a conversation with the head of GRAIL and say, 'Hey, look, if you go this direction or that direction, you know, by the way that's going to convey a benefit'?" (PX7105 (Getty (Guardant) Dep. at 79-80)).

4806. Mr. Getty testified that "ultimately we just have no ability to understand or actually enforce the terms of the contract, and such that, you know, they could continue to operate as they see fit, and ultimately over time, as we talked about, you know, change terms, change pricing, you know, send a technician a few months after they could have. Those things are unknowable and ultimately could be very debilitating to our business." (PX7105 (Getty (Guardant) Dep. at 79-80)).

4807. Mr. Getty explained the "nearly impossible" enforcement of a contract with Illumina: "A contract is only as good as it is enforceable. And ultimately, [Guardant's ability] to investigate adherence to the terms of that contract is nearly impossible." (PX7105 (Getty (Guardant) Dep. at 79-80)).

4808. Mr. Getty testified that Illumina's control over which MCED test developer receives better treatment makes it "very difficult" to audit how equitable Illumina's customer service is: "[T]he [Illumina] individual that was chosen to go to Guardant Health could simply have had a vacation scheduled so that seems like normal course of business. But the person who didn't have a vacation scheduled ended up at GRAIL . . . So even a third party auditor would be – it would be very difficult to gauge like-for-like in terms of services." (PX7105 (Getty (Guardant) Dep. at 85-86)).

4809. [redacted]

4810. [redacted]

4811. A customer that suspects Illumina is in breach of its commitments in the open offer would not know whether it has access to prerelease products at the same time as Grail unless Illumina chose to disclose this information to the customer. (Berry (Illumina) Tr. 7009-01).

4812. A customer that suspects Illumina is in breach of its commitments in the open offer would not know how quickly Illumina repairs Grail or its competitors' equipment. (Berry (Illumina) Tr.700).

4813. A customer that suspects Illumina is in breach of its commitments in the open offer would not know how fast Grail or its competitors receive service and support from Illumina. (Berry (Illumina) Tr. 700).

4814. Under the terms of the open offer, it may take 120 days for a customer to resolve a dispute with Illumina if the customer proceeds with arbitration. (Berry (Illumina) Tr. 721-23).

4815. Under the terms of the open offer, Grail is not subject to the dispute resolution terms of the open offer. (Berry (Illumina) Tr. 724).

4816. Under Section 12(a) of the open offer, Illumina agrees to an annual audit of its compliance with commitments in the open offer. (Berry (Illumina) Tr. 697-99).

4817. Separate from the annual audit, Illumina's compliance with its commitments in the open offer may be audited if a customer has a "good faith basis" for alleging that Illumina is in breach of a commitment in the open offer. (Berry (Illumina) Tr. 699).

4818. Illumina decides if the customer's suspicion of a breach rises to a good faith basis. (Berry (Illumina) Tr. 699-700).

4819. Illumina considers "customer-specific information related to sales, order history, service and support to be all confidential information." (Berry (Illumina) Tr. 647). For example, Ms. Berry testified at trial that Illumina considers the products that a customer purchases and the prices that a customer pays to be confidential information. (Berry (Illumina) Tr. 647-48).

4820. A customer that suspects Illumina is in breach of its commitments in the open offer would not know what prices its competitors are paying for Illumina's products. (Berry (Illumina) Tr. 700).

4821. A customer that suspects Illumina is in breach of its commitments in the open offer would not know what products its competitors are purchasing from Illumina. (Berry (Illumina) Tr. 700).

4822. Outside of the annual audit process, a customer that suspects Illumina is in breach of its commitments in the open offer would not know whether they have access to the same products as Grail. (Berry (Illumina) Tr. 701).

4823. [redacted]

4824. [redacted]

(1) MCED Test Developers Will Not Know What Products Grail Has Access To, What Services Grail Received From Illumina, or What Prices Grail Pays Illumina

4825. Ms. Berry testified that certain information, such as a customer's order information and service reports, is confidential and one customer would not have access to another customer's information). (PX7076 (Berry (Illumina) Dep. at 81; 291)).

4826. Ms. Berry testified that under the Open Offer, customers would not be able to know in real-time what prices its competitors are paying for Illumina products. (PX7076 (Berry (Illumina) Dep. at 291-92)).

4827. Ms. Berry testified that under the Open Offer, a customer would not know in real-time what products its competitors are purchasing from Illumina. (PX7076 (Berry (Illumina) Dep. at 292)).

4828. Ms. Berry testified that under the Open Offer, a customer would not know in real-time how quickly Illumina repairs its competitors' equipment. (PX7076 (Berry (Illumina) Dep. at 292)).

4829. Mr. Getty testified that under the Open Offer there is no way for Guardant to know what products GRAIL has access to. (PX7105 (Getty (Guardant) Dep. at 87-88) ("Q. Is there

any way for Guardant to known when that – the 45-day clock begins in which Guardant should have access to the same products as GRAIL? A. No. And even if there was an ability to do so, it would be largely unimportant because ultimately, you know, if we go back to the example of a product being developed and, you know, the interaction of a test with that product, product being, say, a sequencer, imagine a scenario where the, you know, head of GRAIL's research and development speaks with the heads of Illumina's sequencer development, the head of Illumina's sequencer development says, you know, "Ultimately we will have this technology available on" such and such date. And GRAIL's R&D engine is able to ramp up quickly in order to take advantage of that technological advance much faster than the competitive set. So, you know, whether or not we have even an ability to see it, which we wouldn't, ultimately there's also additional impacts that would be negative to Guardant, relatively speaking, from the combined company.")).

4830. [redacted]

4831. [redacted]

4832. [redacted]

4833. [redacted]

4834. [redacted]

4835. [redacted]

4836. [redacted]

4837. Mr. Getty testified that there is no way for Guardant to know what level of service Grail is receiving from Illumina. (PX7105 (Getty (Guardant) Dep. 84)).

4838. Mr. Getty testified that "there's absolutely no way to even gauge the value of that service. And so when I read things like 'service,' put it in quotes, it's a rather broad terminology. They could provide a service with a technician who, you know, just joined Illumina yesterday and has zero years of experience, and GRAIL could end up with the individual who has 25 years of experience and has been at GRAIL and worked with them ostensibly all the time. And so in short, we wouldn't know that differential, No. 1. And No. 2, if that differential exists, it conveys a very different value of service. So a term like ['Access to Service'] is largely – you know it's – it does not convey any benefit or frankly any value to Guardant Health." (PX7105 (Getty (Guardant) Dep. 84-85)).

4839. [redacted] (Getty (Guardant) Tr. 2544 (*in camera*)).

4840. [redacted] (Getty (Guardant) Tr. 2547 (*in camera*)).

4841. [redacted] (Getty (Guardant) Tr. 2561 (*in camera*)).

4842. [redacted] (Getty (Guardant) Tr. 2562 (*in camera*)).

(2) Illumina's Audit Provision Is Flawed

4843. The Open Offer Enforcement term provides an Audit subterm which states "Illumina agrees to conduct an annual audit by an independent third-party auditor selected by Illumina from among the "Big 4" accounting firms to audit Illumina's compliance with the commitments set forth herein. Illumina will provide Customers with a written report (with reasonable redactions) confirming compliance with the commitments set forth herein. Illumina shall provide cooperation, including access to necessary books and records, in support of any audit conduct. To the extent Customer has a good faith basis for alleging that Illumina is in breach of a commitment contained herein, Illumina shall engage an auditor to assess Customer's allegation separate from and in addition to Illumina's annual audit." (PX0064 § 12.a. (Illumina Open Offer Agreement, Mar. 29, 2021)).

4844. [redacted]

4845. [redacted]

[redacted]

4846. [redacted]

4847. Mr. Getty testified that if "Illumina willfully breaches their commitment on day one of a year and the report is delivered on day 365, and over that period of time Illumina was able to take that breach and turn it into a significant competitive advantage for GRAIL by advancing their technology ahead of Guardant's" then "that would be extremely, extremely problematic and perhaps even pushing us to the nonexistence, if you will, over the course of a year." (PX7105 (Getty (Guardant) Dep. at 90-91)).

4848. [redacted] (Getty (Guardant) Tr. 2555 (*in camera*)).

4849. [redacted] (Getty (Guardant) Tr. 2557 (*in camera*)).

4850. Mr. Getty testified that under Section 12.a. of Illumina's Open Offer, Guardant would only receive a report of Illumina's compliance once a year. (PX7105 (Getty (Guardant) Dep. at 89-90)).

4851. Mr. Getty testified that the impact on Guardant from only learning that Illumina breached its commitments one year after the breach would be "very significant." (PX7105 (Getty (Guardant) Dep. at 89-91)).

4852. [redacted]

4853. [redacted]

[redacted]

4854. [redacted]

[redacted]

4855. [redacted]

4856. [redacted]

4857. [redacted]

[redacted]

4858. Illumina had not engaged an auditor when Respondents' expert, Mr. Rock, prepared his expert report. (RX6003 (Rock Trial Dep. at 82)).

4859. Neither Illumina nor anyone else had determined the specific procedures that would be employed by an auditor when Mr. Rock prepared his expert report. (RX6003 (Rock Trial Dep. at 82)).

4860. The specific procedures that would be employed by an auditor had not been established when Mr. Rock prepared his expert report. (RX6003 (Rock Trial Dep. at 82)).

4861. The specific procedures that would be employed by an auditor had not been established at the time of Mr. Rock's deposition. (RX6003 (Rock Trial Dep. at 83)).

4862. [redacted]

4863. Ms. Berry testified that she did not know whether other customers would have access to a report regarding a specific customer's complaint. (PX7076 (Berry (Illumina) Dep. at 287)).

4864. Ms. Berry testified that the auditor may potentially have access to Illumina's service reports, but she could not confirm. (PX7076 (Berry (Illumina) Dep. at 288-89)).

4865. Ms. Berry testified that she did not believe that notes related to customer negotiations constitute "books and records" for purposes of the open offer, but she could not confirm. (PX7076 (Berry (Illumina) Dep. at 289)).

4866. Ms. Berry testified that she did not know whether a customer would have to give approval before the auditor has access to their confidential information. (PX7076 (Berry (Illumina) Dep. at 290-91)).

(a) It Is Unclear When a Customer's Allegation Rises to a "Good Faith Basis"

4867. Ms. Berry testified that she did not know specifically who makes the determination of whether a customer's allegation rises to a good faith basis. (PX7076 (Berry (Illumina) Dep. at 284-85)).

4868. Ms. Berry testified that she did not know whether Illumina has to agree that a customer has a good faith basis for alleging Illumina is in breach of a commitment. (PX7076 (Berry (Illumina) Dep. at 285)).

4869. Ms. Berry testified that Illumina's open offer letter does not state whether a customer's suspicion that the agreement has been violated constitutes a good faith basis for an audit. (PX7076 (Berry (Illumina) Dep. at 296-97) ("Can I point to the language that specifically describes that? Not specifically.")).

4870. Customers have to rely on Illumina's "intent" and "spirit" under the open offer to determine what constitutes a good faith basis for bringing an audit. (*See* PX7076 (Berry (Illumina) Dep. at 296-97)).

4871. Ms. Berry testified that she was not aware of how customers would know what Illumina's "spirit" is under the open offer. (PX7076 (Berry (Illumina) Dep. at 297) ("Q. And how would customers be aware of the spirit? A. I'm not sure that there's a basis for them to be aware of the spirit")).

4872. [redacted]

4873. Mr. Getty testified that he did not know who would decide whether Guardant had a good faith basis under Section 12.a. of the Open Offer. (PX7105 (Getty (Guardant) Dep. at 92)).

(b) Customers Do Not Know What Constitutes a "Good Faith Basis"

4874. [redacted]

4875. [redacted]

4876. [redacted]

4877. Additionally, Mr. Getty testified that Guardant's "lack of visibility to . . . things makes it almost impossible to determine when a potential breach has happened." (PX7105 (Getty (Guardant) Dep. at 91)).

4878. Mr. Getty further pointed out that "even in the context that you get over the hurdle defining what good faith means, you then get over the hurdle of being in good enough standing apparently to render that complaint and then, you know, you get over the hurdle of having someone look into that Complaint, you've lost the thing you can't get back, which is time, and potentially cementing of a significant competitive advantage that can't be undone. So ultimately the ability to [bring a good faith basis] doesn't really convey much value to Guardant Health." (PX7105 (Getty (Guardant) Dep. at 92)).

(c) Ms. Guerin-Calvert's Audit Analysis Does Not Meet Her Own Report's Standards

4879. At the time of her report, Respondent's Expert, Ms. Guerin-Calvert, wrote that, with respect to the audit plan, "the description and commitments codified in the Open Offer are not detailed." (RX3865 (Guerin-Calvert Rebuttal Report) ¶ 105; RX6002 (Guerin-Calvert Trial Dep. at 129)).

4880. Ms. Guerin-Calvert agreed that an auditor of Illumina's compliance with its commitments pursuant to the Open Offer does not determine whether Illumina violated those commitments. (RX6002 (Guerin-Calvert Trial Dep. at 132)).

4881. Ms. Guerin-Calvert testified that the auditing process is not "100 percent certain" and breaches of the firewall "may not end up falling to [the auditor] in a form that [is] detectable." (RX6002 (Guerin-Calvert Trial Dep. at 133)).

4882. Ms. Guerin-Calvert confirmed that Illumina has not committed to post the results of its audits on its website. (RX6002 (Guerin-Calvert Trial Dep. at 140)).

4883. Ms. Guerin-Calvert testified that she was not aware of whether the audit provided to customers would be the same as a potential compliance report offered to the FTC. (RX6002 (Guerin-Calvert Trial Dep. at 140)).

4884. Ms. Guerin-Calvert testified that if a customer has "a [good faith] basis for believing that Illumina is in breach of a commitment, then Illumina would engage an auditor to assess the allegation . . . ." (RX6002 (Guerin-Calvert Trial Dep. at 87); RX3865 (Guerin-Calvert Rebuttal Report) ¶¶ 38, 105).

4885. Ms. Guerin-Calvert testified that her Expert Report does not state a particular economic test for assessing an Illumina customer's "good faith basis" alleging that Illumina has breached a commitment in the Open Offer. (RX6002 (Guerin-Calvert Trial Dep. at 130)).

4886. Ms. Guerin-Calvert testified that she is not offering a legal opinion on the definition of "good faith." (RX6002 (Guerin-Calvert Trial Dep. at 130)).

4887. Ms. Guerin-Calvert agreed that Illumina's Open Offer does not address who decides if a customer's allegation of a breach has a good faith basis. (RX6002 (Guerin-Calvert Trial Dep. at 130-31)).

4888. Ms. Guerin-Calvert testified that the Open Offer does not specify the criteria for determining or how to decide whether a customer's allegation of a breach has a good faith basis. (RX6002 (Guerin-Calvert Trial Dep. at 131)).

4889. Ms. Guerin-Calvert agreed that the Open Offer does not provide a time frame or a limit to how long a decisionmaker has to determine whether a customer's allegation of a breach has a good faith basis. (RX6002 (Guerin-Calvert Trial Dep. at 131)).

(d) Mr. Rock's Report Describes an "Illustrative" Set of Agreed-Upon Procedures That Illumina Has Not Actually Undertaken

4890. [redacted]} (PX7135 (Rock Dep. at 59 (*in camera*))).

4891. In his report, Mr. Rock drafted an "illustrative list of potential agreed-upon procedures" to be used by Illumina's auditor. (RX6003 (Rock Trial Dep. at 88); RX3870 (Rock Rebuttal Report) ¶ 27). Mr. Rock conceded that his "illustrative" list is not a list of the procedures that the auditor and Illumina have agreed will be employed. (RX6003 (Rock Trial Dep. at 88)).

4892. Mr. Rock does not know how the actual procedures employed by Illumina in connection with its Open Offer would compare with the "illustrative" procedures he lists in his report: "I don't know. Since I don't know what will be performed, I can't answer that." (RX6003 (Rock Trial Dep. at 88)).

4893. Mr. Rock testified that he does not know whether an auditor engaged by Illumina would issue an agreed-upon procedures report. (RX6003 (Rock Trial Dep. at 77)).

4894. Mr. Rock testified that he believes an auditor's report, if issued, would likely be prepared consistent with Public Company Accounting Oversight Board (PCAOB) standards for agreed-upon procedures. (RX6003 (Rock Trial Dep. at 89)).

4895. Mr. Rock's illustrative list of agreed-upon procedures includes the word "test" to describe several procedures. (RX6003 (Rock Trial Dep. at 91)). Every time the word "test" appears in Mr. Rock's report, it could refer to four or ten or to thirty actual procedures, which are not identified in Mr. Rock's report. (RX6003 (Rock Trial Dep. at 92)).

4896. Mr. Rock cites AT Section 201 of the PCAOB's standards for agreed-upon procedures in his report. (RX6003 (Rock Trial Dep. at 90; RX3870 (Rock Rebuttal Report) ¶ 19 n.6). Section 201.16 states, "Terms of uncertain meaning (such as general review, limited review, check, or test) should not be used in describing the procedures unless such terms are defined within the agreed-upon procedures." (RX6003 (Rock Trial Dep. at 90); PX0347 (Public Company Accounting Oversight Board AT Section 201.16 (Agreed-Upon Procedures Engagements), https://pcaobus.org/oversight/standards/attestation-standards/details/AT201)).

4897. Mr. Rock's report does not identify any illustrative agreed-upon procedures at all for Section 4.d (Development Agreement) of the Open Offer. (RX6003 (Rock Trial Dep. at 92)).

4898. Mr. Rock's report does not state how compliance with section 5.h (Short Term Projects) of the Open Offer could be tested, and Mr. Rock did not attempt to offer an opinion on what procedures would be sufficient to test compliance with section 5.h (Short Term Projects) of the Open Offer. (RX6003 (Rock Trial Dep. at 91-92)).

4899. Mr. Rock's report does not identify any illustrative agreed-upon procedures at all relating to Section 6 (FDA) of the Open Offer. (RX6003 (Rock Trial Dep. at 92-93)).

4900. Mr. Rock's report does not identify any illustrative agreed-upon procedures at all relating to Section 8 (Short Supply) of the Open Offer. (RX6003 (Rock Trial Dep. at 93)).

4901. Mr. Rock's report does not identify any illustrative agreed-upon procedures for testing compliance with Section 10.a (Confidentiality) of the Open Offer. (RX6003 (Rock Trial Dep. at 96)).

(e) Mr. Rock's Report Describes Compliance Attestation Procedures That Illumina Has Not Actually Undertaken

4902. Mr. Rock claimed in his expert report that "[t]o establish effective compliance attestation procedures, Illumina will need to undertake" ten listed items. (RX3870 (Rock Rebuttal Report) ¶ 26).

4903. In his trial deposition, Mr. Rock claimed that "[n]ot all of these [items] are necessarily required" and that Illumina would "need [only] to undertake the vast majority of" the items as part of its offer audit process. (RX6003 (Rock Trial Dep. at 52, 84-85)). Mr. Rock

admitted that this trial testimony was "slightly different" from what he wrote in his expert report. (RX6003 (Rock Trial Dep. at 84-85)).

4904. Mr. Rock's report makes no claim that Illumina has actually undertaken any of the necessary ten compliance attestation procedures he lists in Paragraph 26 of his report. (RX6003 (Rock Trial Dep. at 85-86); RX3870 (Rock Rebuttal Report) ¶ 26).

4905. Mr. Rock's report does not state that Illumina has established evaluation criteria for each Open Offer contract obligation. (RX6003 (Rock Trial Dep. at 86)).

4906. Mr. Rock's report does not state that Illumina has developed and documented systems, policies, and procedures that would allow for the efficient and accurate tracking and reporting of the evaluation criteria, data, and calculations. (RX6003 (Rock Trial Dep. at 86)).

4907. Mr. Rock's report does not state that Illumina has developed a reporting framework to evaluate compliance with the Open Offer. (RX6003 (Rock Trial Dep. at 86)).

4908. Mr. Rock's report does not state that Illumina has developed an internal audit program to monitor and test compliance with the Open Offer. (RX6003 (Rock Trial Dep. at 87)).

4909. Mr. Rock's report does not state that Illumina has engaged an independent compliance auditor. (RX6003 (Rock Trial Dep. at 87)).

4910. Mr. Rock's report does not state that Illumina has established data room content and access procedures. (RX6003 (Rock Trial Dep. at 87)).

4911. Mr. Rock's report does not state that Illumina has established an Open Offer compliance hotline. (RX6003 (Rock Trial Dep. at 87)).

4912. Mr. Rock's report does not state that Illumina has developed agreed-upon procedures that address concerns that have been raised. (RX6003 (Rock Trial Dep. at 87)).

4913. In preparing his report, Mr. Rock did not go through the Open Offer's terms and analyze what kind of evidence would be available to test compliance with each term. (RX6003 (Rock Trial Dep. at 94)).

4914. In preparing his report, Mr. Rock did not perform any procedures to check compliance or verify the records of Illumina. (RX6003 (Rock Trial Dep. at 93)).

(f) An Auditor Would Not Certify Compliance with the Open Offer

4915. Mr. Rock agreed that "the objective of the [Independent Compliance Auditor's] agreed-upon procedures is to present specific findings to assist customers in evaluating an entity's compliance with specified requirements or the effectiveness of an entity's internal control over compliance based upon procedures agreed upon by the customers." (RX6003 (Rock Trial Dep. at 78)).

4916. Mr. Rock testified that the auditor "would not offer an affirmative opinion of compliance" and "is not going to issue a conclusion that the open offer has been complied with." (RX6003 (Rock Trial Dep. at 77-79)).

4917. Mr. Rock stated that "the auditor is not going to want to try to opine on compliance specifically since that would likely be a legal opinion, and most auditors or auditors aren't generally practicing law or issuing legal opinions." (RX6003 (Rock Trial Dep. at 31)).

4918. Mr. Rock further testified that an auditor would not be able to say affirmatively that there had been no breaches of confidentiality. (RX6003 (Rock Trial Dep. at 96)).

(g) Mr. Rock Testified That Gaps Could Exist in the Open Offer and That Auditing Would Not Necessarily Address All Customer Concerns

4919. Mr. Rock identified "illustrative categories" of procedures that might be employed by Illumina in connection with a Grail firewall. (RX6003 (Rock Trial Dep. at 67)).

4920. Mr. Rock testified that the "illustrative categories" of procedures that might be employed by Illumina in connection with a Grail firewall would not necessarily address all customer concerns. (RX6003 (Rock Trial Dep. at 71)).

4921. Mr. Rock testified that "the auditor can help and the company will improve their procedures I believe [with respect to firewall confidentiality], the agreed-upon procedures over time, and the company will try to eliminate gaps, [and] try to improve compliance over time." (RX6003 (Rock Trial Dep. at 72)).

4922. Mr. Rock testified that even with effective audit procedures, "[t]here might be degrees of gradation on whether, you know, you can close all the holes in" supply contracts. (RX6003 (Rock Trial Dep. at 42-43)).

4923. Mr. Rock testified that it is not necessary for an audit to discover all events of noncompliance for him to consider the audit "very effective." (RX6003 (Rock Trial Dep. at 46)).

4924. Mr. Rock conceded that "it's possible that [the auditor] may not be able to catch" every instance of inappropriate disclosure of confidential information within Illumina: "[I]t's my opinion that they would not have certainty that they've caught all of those potential breaches that you describe, on the phone, in the bathroom, at a restaurant." (RX6003 (Rock Trial Dep. at 96-97)).

4925. Mr. Rock stated that "sometimes one – one item, one supply item, can interrupt the production of everything" for a customer. (RX6003 (Rock Trial Dep. at 41)).

4926. Mr. Rock did not consider any monitor appointments from any FTC or DOJ antitrust cases in forming his opinions. (RX6003 (Rock Trial Dep. at 99)).

4927. Mr. Rock's report cites an FTC blog about a matter involving Coke and Pepsi, but Mr. Rock testified that he did not review any documents relating to the matter beyond the blog post in drafting his report and did not talk to the FTC-appointed monitor in the matter. (RX6003 (Rock Trial Dep. at 99-101)). Mr. Rock testified that he did not know whether Coke or Pepsi breached any firewall provisions or whether the monitor was able to resolve any problems that may have arisen in that matter, or if so, how much time it took to resolve any problems: "I have no idea if the monitor performed their procedures, what their findings were or what any resolution was. I do not know the – any of those." (RX6003 (Rock Trial Dep. at 101-102)).

(3) Any Breach of the Open Offer Would Be Difficult for MCED Test Developers to Resolve

(a) A Dispute Related to the Open Offer Would Place MCED Test Developers in the Difficult Position of Negotiating, or Perhaps Even Litigating, Against the Sole Supplier of a Critical Input for MCED Tests

4928. [redacted]

4929. [redacted]

4930. [redacted]

4931. Singlera's Dr. Gao acknowledged the difference in resources in any battle with Illumina, stating, "We are the small ants. We cannot fight a war. We're hoping the giants will fight the war." (PX7042 (Gao (Singlera) IHT at 89)).

4932. [redacted]

4933. [redacted]

[redacted]

(4) Illumina's Arbitration Provision Is Flawed

4934. The Open offer Arbitration term states in part: "If any dispute arises from or relates to this Supply Agreement, including as a result of a dispute over terms in a separate agreement that incorporates the terms herein (the "Dispute"), other than claims involving infringement, validity, or enforceability of Intellectual Property Rights (whether Illumina's or Customer's), or about the scope of Intellectual Property Rights in an agreement, Illumina and Customer (each a "party" and together the "parties") shall submit the matter to confidential binding arbitration to determine final terms and conditions of the supply agreement, or to settle the dispute as to the terms of a supply agreement." (PX0064 at 010 (Illumina Open Offer agreement, Mar. 29, 2021)).

4935. Ms. Berry testified that if a customer disputes the auditor's findings, they would engage in an arbitration with Illumina. (PX7076 (Berry (Illumina) Dep. at 286)).

4936. Arbitration takes time and involves costs. (deSouza (Illumina) Tr. 2456; PX7076 (Berry (Illumina) Dep. at 298-99); PX7105 (Getty (Guardant) Dep. at 93)).

4937. Mr. Getty testified that the impact enforcing a breach of contract would have on Guardant is extensive. Specifically, he testified "the cost of individual's time within the organization, and the bandwidth necessary to spend with those proceedings, to ensure that, you know, we put our best foot forward" would be one such impact. (PX7105 (Getty (Guardant) Dep. at 93-94)).

4938. The cost of arbitration "while not defined in dollar amounts, ties up [Guardant's] time and energy and resources that could be deployed against development of tests for the future state. It could tie up their time for development of tests in the current state across all of the different areas that we exist in today[.]" (PX7105 (Getty (Guardant) Dep. at 93-94)).

4939. Mr. Getty also testified that arbitration with Illumina would slow down Guardant's innovation and have a very significant impact on patient care "because ultimately [Guardant would be] tied up dealing with the arbitration around a matter that we have very limited visibility into." (PX7105 (Getty (Guardant) Dep. at 95)).

4940. Mr. Getty testified that "if you were to spend a year in arbitration trying to figure out whether GRAIL had a competitive advantage that eventually, you know, sort of played out in terms of a differentiated test offering, and physicians start adopting, you know, whether or not Guardant is successful a year and a half later with an arbitration case may be frankly rendered useless because ultimately by that time, they've cemented such a position in the marketplace that they've been able to accelerate their market share well beyond what we could ever catch up to." (PX7105 (Getty (Guardant) Dep. at 95-96)).

4941. Mr. Getty testified that there is a risk to getting into a contractual dispute with their sole supplier, Illumina. Specifically, he testified, "[y]ou know, there are significant externalities there. And, you know, as individuals and negotiating partners and partners just in general, as we've all experienced with personal relationships, you know, if you have a negative interaction, it certainly will create dynamics in the future state that may not be positive for that relationship. So, you know, for lack of a better metaphor, poking the bear is not exactly a good idea." (PX7105 (Getty (Guardant) Dep. at 96)).

4942. Mr. Fiedler testified that if FMI were to be in litigation with Illumina it would be a "very unfortunate situation" because "during litigation the business retreats to really focusing on contractual terms and not kind of going the extra mile when it's required." (PX7118 (Fiedler (FMI) Dep. at 84-85)).

4943. Mr. Fiedler testified that being in a contractual dispute with an essential supplier for FMI, such as Illumina, would be a "very grave concern if this would impact deliveries." (PX7118 (Fiedler (FMI) Dep. at 85-86) ("Q. Do you see any issues with being in a contractual dispute with an essential supplier for FMI? [Objections] A. I think the main concern is that as long as the delivery continues during that dispute, then as I said, it's the extra service of the extra flexibility that might be missing. It would be of very grave concern if this would impact deliveries.")).

4944. To complete the entire arbitration process could take up to 120 days. (*See* Berry (Illumina) Tr. 721-23)).

4945. Ms. Berry does not know whether Grail, as an affiliate of Illumina, would have to go through the same 120-day arbitration process. (Berry (Illumina) Tr. 723-24).

4946. Grail, as an affiliate of Illumina now, is not subject to the Open Offer letter. (Berry (Illumina) Tr. 724).

(a) Ms. Guerin-Calvert's Arbitration Analysis Does Not Meet Her Own Report's Standards

4947. Ms. Guerin-Calvert agreed that if there was a dispute between Illumina's CEO and any of Illumina's customers, they would work through Section 12 of the open offer that details the dispute mechanism process. (RX6002 (Guerin-Calvert Trial Dep. at 137-38)).

4948. Ms. Guerin-Calvert testified that it could take up to 120 days for Illumina's customers to resolve a dispute through the dispute mechanism process. (RX6002 (Guerin-Calvert Trial Dep. at 133-34)).

4949. Ms. Guerin-Calvert testified that Illumina's customers have to bear their own costs of arbitration with Illumina. (RX6002 (Guerin-Calvert Trial Dep. at 138)).

4950. By contrast, if there's a dispute between Illumina's CEO and GRAIL, ultimately, Illumina's CEO is responsible for GRAIL's operations. (RX6002 (Guerin-Calvert Trial Dep. at 138)).

l) The Open Offer Cannot Account for Every Way Illumina Can Harm Grail's Rivals Over a 12-Year Term

4951. [redacted] (Berry (Illumina) Tr. 694; PX7076 (Berry (Illumina) Dep. at 222-23 (*in camera*)).

4952. [redacted] (PX2385 (Illumina) at 001 (Text message from N. Berry, Illumina, to K. Peterson, Illumina, Nov. 19, 2020) (*in camera*))).

4953. [redacted] (PX7076 (Berry (Illumina) Dep. at 221) (*in camera*)).

4954. Ms. Berry testified that its "fair to assume" that it's difficult to know every situation that may take place over the course of a 12-year supply agreement because "there's a lot of dynamic things that are happening amongst [Illumina's] customers." (Berry (Illumina) Tr. 694).

4955. [redacted]

4956. [redacted]

4957. [redacted]

4958. [redacted]

[redacted]

4959. [redacted]

4960. Mr. Getty testified that he is unaware of all of the circumstances in which Guardant may need Illumina's assistance over the next 12 years. (PX7105 (Getty (Guardant) Dep. 82)).

4961. Mr. Getty further testified that he is unaware of all the issues that Guardant may face with Illumina as its supplier over the next 12 years because Guardant is "in a rapidly-evolving space that, you know, has remained stagnant very infrequently. And so ultimately just by virtue of the nature of 12 years on, it's challenging to see, but even in the sort of short term, it's difficult to even predict what's going to happen next month." (PX7105 (Getty (Guardant) Dep. 82)).

4962. Guardant's SVP of Commercial, Cancer Screening Core, William Getty, testified that "it's difficult to even predict what's going to happen next month[,]" and that "the risk premium goes up pretty significantly" further out in the contractual term. (PX7105 (Getty (Guardant) Dep. at 82-83)).

4963. Mr. Getty testified that "it's nearly impossible to determine" every contractual term that Guardant would need to ensure that it doesn't have any harm from Illumina's acquisition of Grail. (PX7105 (Getty (Guardant) Dep. 82-83)).

4964. Mr. Getty testified, with regard to identifying every contractual term Guardant would need from Illumina, that "the risk premium goes up pretty significantly relatively speaking when we start talking about terms that are, you know, 12 years on. So it's – it's impossible." (PX7105 (Getty (Guardant) Dep. 82-83)).

4965. Nitin Sood, former Senior Vice President of Products at Guardant, testified "I cannot imagine every way in which the Illumina acquisition of GRAIL could hurt GRAIL's competitors." (PX7090 (Sood (Guardant) Dep. at 146-47)).

4966. [redacted]

4967. [redacted]

4968. [redacted]

[redacted]

4969. [redacted]

4970. [redacted]

4971. [redacted]

4972. [redacted]

4973. [redacted] (PX6090 (Scott Morton Report) ¶ 313 (*in camera*)).

m) Potential Reputational Damage Will Not Prevent Illumina from Violating Its Contractual Commitments to MCED Customers

4974. As provided above in Section V. (Illumina NGS Is a Necessary Input to MCED Tests), MCED test developers testified unanimously that they have no alternative NGS options for their MCED tests.

4975. After Illumina closed its acquisition of Grail despite the European Commission's standstill order, Illumina told investors in an SEC filing that consummating the transaction when it did could lead to "other adverse consequences to, among other things, its reputation . . . ." (PX0378 at 004-05 (Illumina Form 8-K, Aug. 18, 2021)).

4976. Illumina's CEO Mr. deSouza acknowledged at trial that Illumina decided to close the transaction despite the potential risk to its reputation. (deSouza (Illumina) Tr. 2236-37).

4977. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 99 (*in camera*)).

4978. As provided in Sections VII.A. (Illumina Has the Ability to Harm Grail's Rivals) and VII.B. (Illumina Has the Incentive to Lessen Competition in the U.S. MCED Test Market by Disadvantaging Grail's Rivals), Illumina has the ability to use its position as the sole NGS supplier to MCED test developers to hinder, alter, foreclose, or delay the progress of MCED test developers to the benefit of Grail.

4979. [redacted]

4980. [redacted]

4981. [redacted]

4982. [redacted]

4983. [redacted]

4984. [redacted]

[redacted]

4985. [redacted]

4986. Ken Song of Omniome previously worked at Ariosa, an NIPT competitor of Illumina. Mr. Song testified on the ways Illumina would act in the past when it was vertically integrated against Ariosa and how because of their position as the "only solution" in the NGS market, they could get away with it:

> So I'll speak based on my prior experience at Ariosa Diagnostics, where we were in situations where we were trying to sell our system, which ended up being a nonsequencing-based option, where Illumina would go to our customers or our prospective customers and tell them, well, you know -- you know, that's -- that either doesn't have adequate patent protection or if you do that, you know, not only is the company infringing, but you're potentially liable for infringing as well.
>
> So, you know, they're not saying that they're going to sue their customer, but they're definitely insinuating that that's a possibility, and I think they also use that to perhaps threaten the customer – the customer might still need to use Illumina's sequencing products for other applications, right, not just specific to -- in my case of Ariosa, on behalf of Ariosa, in the case of NIPT, that was just one application.
>
> But if a customer needs Illumina for, like, 80 percent of their other tests, you know, I think Illumina indirectly sort of said, well, you know, if you need to be reliant upon us for that other stuff, you should really use us for everything.
>
> So, look, I mean, they have been around. They're super smart. They're super successful. I think they have an army of lawyers there. So they know kind of -- I would anticipate they kind of know what they might be able to get away with, but it's -- but I would -- I would say it's sort of a -- you know, they're kind of the big bully, and I remember I thought of this back in my Ariosa days, that they literally do -- I believe they literally use their IP as a weapon to try and control the marketplace, and people are scared of them because of that, because

they're really the only solution that's out there in a pretty large and expanding NGS market."

(PX7071 (Song (Omniome) IHT at 43-44)).

4987. [redacted] (PX7071 (Song (Omniome) IHT at 44) (*in camera*)).

4988. [redacted] (PX7071 (Song (Omniome) IHT at 45) (*in camera*)).

n) Illumina Does Not Need to Commit a Blatant Violation of the Open Offer to Materially Affect the Competitiveness of MCED Test Developers

(1) Rather Than Refusing to Sell MCED Test Developer Reagents Outright, Illumina Can Gradually Optimize Its Reagents to Work Best on Galleri Without Optimizing Its Reagents for Other MCED Tests

4989. [redacted]

4990. [redacted]

4991. [redacted]

4992. [redacted]

o) Customers Do Not Believe Open Offer Will Resolve Concerns

(1) [redacted]

4993. Mr. Getty, Guardant's SVP of Commercial, Cancer Screening Core, testified, "the [open] offer that is put forward is nothing more than a paper tiger. It's very difficult to understand how that would alleviate our concerns about a combined GRAIL and Illumina organization," adding that "[u]ltimately, . . . we don't have an option." (PX7105 (Getty (Guardant) Dep. at 78-79)).

4994. [redacted]

4995. [redacted]

4996. [redacted]

4997. [redacted]

4998. [redacted]

4999. [redacted]

5000. [redacted]

5001. [redacted]

5002. [redacted]

5003. [redacted]

5004. [redacted]

[redacted]

5005. [redacted]

5006. [redacted]

5007. [redacted]

5008. [redacted]

5009. [redacted]

[redacted]

5010. [redacted]

5011. [redacted]

5012. [redacted]

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

5013. As discussed in Section V.G. above, even if a new company develops an NGS platform, significant barriers to entry exist, no NGS platform that may enter appears to be a viable option for MCED tests, and Illumina's product pipeline will improve upon its existing market leading and best-in-class NGS option for MCED tests.

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

5014. Dr. Rothman testified that, according to the Horizontal Merger Guidelines, "it is incumbent upon the merging parties to substantiate their claimed efficiencies such that the following could be verified: the likelihood and magnitude of each claimed efficiency; how and when each claimed efficiency would be achieved, including the costs of achieving each claimed efficiency; how each claimed efficiency would enhance the merged firm's ability and incentive to compete; and why each claimed efficiency would be merger-specific." (PX7140 (Rothman Trial Dep. at 15-16)).

5015. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 42 (*in camera*); PX0338 at 029-031, (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

5016. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 42 (*in camera*); PX0338 at 029-031, (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

5017. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 42 (*in camera*); PX0338 at 029-031, (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

5018. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 42 (*in camera*); PX0338 at 029-031, (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

5019. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 43 (*in camera*); PX0338 at 029-031, (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

5020. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 43 (*in camera*); PX0338 at 029-031 (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

5021. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 43 (*in camera*); PX0338 at 029-031 (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

5022. At trial, Mr. Strom, a managing director of Morgan Stanley's healthcare investment banking group who advised Grail, testified that companies can fail to realize synergies from mergers and acquisitions. (Strom (Morgan Stanley) Tr. 3586-88).

5023. At trial, Mr. Strom testified that mergers and acquisitions have execution risks. (Strom (Morgan Stanley) Tr. 3586-88).

5024. At trial, Mr. Strom testified that corporate cultures can fail to mesh post-acquisition. (Strom (Morgan Stanley) Tr. 3587).

5025. At trial, Mr. Strom testified that key employees can decide to leave because of a merger. (Strom (Morgan Stanley) Tr. 3587).

5026. When Illumina first considered setting up Grail as a separate company, in 2015, it noted that success "will require that the company is the place with the best people in the world of cancer screening who we could not recruit to Illumina." (PX2006 (Illumina) at 001 (Email from Rick Klausner, Illumina, to Marc Stapley, Illumina, et al., Jul. 14, 2015)).

5027. At trial, Mr. Strom agreed that, post-merger, Illumina could have a harder time attracting the type of talent that is drawn to a start-up like Grail. (Strom (Morgan Stanley) Tr. 3587).

5028. When Illumina first considered setting up Grail as a separate company in 2015, Rick Klausner, Illumina's Chief Medical Officer at the time, stated that "Illumina has no IP, no special data or expertise or idea to put into this company." (PX2006 (Illumina) at 001 (Email from Rick Klausner, Illumina, to Marc Stapley, Illumina, et al., Jul. 14, 2015)).

1. Acceleration of Galleri

a) FDA Acceleration

(1) Background on FDA Approval

5029. The FDA classifies MCED tests as Class III medical devices. (*See, e.g.*, PX7099 (Febbo (Illumina) Dep. at 83-84)).

5030. Medical devices categorized as Class III devices are considered to be the highest-risk category of medical devices. (PX7056 (Silvis (Tempus) IHT at 37)).

5031. The FDA typically requires a developer of a Class III medical device to submit an application for PMA approval in order to determine the safety and efficacy. (PX7056 (Silvis (Tempus) IHT at 37)).

5032. 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)).

(2) The Claimed FDA Acceleration Efficiency Is Not Verifiable Because It Is Unlikely That Illumina Can Accelerate FDA Approval Compared to Grail on Its Own

5033. Dr. Rothman concluded that Respondents' experts' claimed acceleration efficiency is not a cognizable efficiency. (PX7140 (Rothman Trial Dep. at 17).

5034. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 28 (*in camera*)).

5035. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 51 (*in camera*)).

5036. Dr. Aravanis testified that the "regulatory aspects" of Illumina's potential assistance to Grail are "modest," and that "it's unlikely that there's any company out there that would feel that the regulatory aspects related to site-specific PMA are that meaningful." (PX7065 (Aravanis (Illumina) IHT at 229-31)).

5037. Dr. Aravanis testified that "in terms of achieving a site-specific PMA which probably represents for cancer screening . . . all that will be achieved in the next five, maybe ten years, the regulatory aspect in the United States is probably pretty minimal and may or may not be a significant determinant of company success." (PX7065 (Aravanis (Illumina) IHT at 228)).

5038. [redacted] } (PX6092 (Rothman Rebuttal Report) ¶ 52 (*in camera*)).

5039. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 28 (*in camera*); PX7140 (Rothman Trial Dep. at 20) (*in camera*)).

(a) [redacted]

5040. 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)).

5041. [redacted] (PX5042 (Illumina) [redacted] (*in camera*); Freidin (Grail) Tr. 3138; *see also* PX6092 (Rothman Rebuttal Report) ¶ 46 (*in camera*)).

5042. [redacted] } (PX2163 (Illumina) at 025 [redacted] (*in camera*); *see* PX6092 (Rothman Rebuttal Report) ¶ 46 (*in camera*)).

5043. Illumina's claimed FDA acceleration efficiency is not reflected in the base case of Illumina's financial model for its acquisition of Grail. (Febbo (Illumina) Tr. 4361).

5044. [redacted] (Qadan (Illumina) Tr. 4228 (*in camera*)).

5045. [redacted] (Qadan (Illumina) Tr. 4228 (*in camera*)).

5046. [redacted] (Qadan (Illumina) Tr. 4228 (*in camera*)).

5047. [redacted] (Qadan (Illumina) Tr. 4229 (*in camera*)).

5048. [redacted] (Qadan (Illumina) Tr. 4229 (*in camera*)).

5049. [redacted] (PX5042 (Illumina) [redacted] (*in camera*); *see* PX6092 (Rothman Rebuttal Report) ¶ 47 (*in camera*)).

5050. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 47 (*in camera*); *see* PX5042 (Illumina) [redacted] (*in camera*)).

5051. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 47 nn. 79-80 (*in camera*); PX5042 (Illumina) [redacted] (*in camera*)).

5052. [redacted] (Qadan (Illumina) Tr. 4229-30 (*in camera*)).

5053. [redacted] (Qadan (Illumina) Tr. 4230-31 (*in camera*)).

5054. [redacted] (Qadan (Illumina) Tr. 4231 (*in camera*)).

5055. [redacted] (Febbo (Illumina) Tr. 4431 (*in camera*)).

5056. [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 46-49 (*in camera*); PX7140 (Rothman Trial Dep. at 25) (*in camera*)).

5057. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 49 (*in camera*); PX7140 (Rothman Trial Dep. at 27) (*in camera*)).

5058. [redacted] (PX7140 (Rothman Trial Dep. at 26) (*in camera*); *see also* PX6092 (Rothman Rebuttal Report) ¶ 49 (*in camera*)).

5059. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 47 (*in camera*); PX5042 (Illumina) [redacted] (*in camera*)).

5060. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 49 (*in camera*)).

5061. [redacted] (*See, e.g.*, PX5030 (Illumina) at 016 [redacted] (*in camera*)).

5062. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 19 (RFA No. 24) (*in camera*)).

5063. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 22 (RFA No. 29) (*in camera*)).

5064. Illumina has not provided Grail with an estimate of how much earlier Illumina expects Galleri to receive FDA approval as a result of the transaction. (Freidin (Grail) Tr. 3145).

5065. Mr. Aaron Freidin leads Grail's financial projections and analysis team ("FP&A"). (Freidin (Grail) Tr. 3144).

5066. Mr. Freidin testified at trial that Grail did not prepare its own deal model. (Freidin (Grail) Tr. 3140).

5067. At trial, Mr. Freidin testified that Grail "hadn't done any modeling as if Grail was acquired by Illumina." (Freidin (Grail) Tr. 3141).

5068. Grail has not performed any analysis of any potential synergies from the Illumina transaction. (Freidin (Grail) Tr. 3151-52).

5069. When Grail agreed to combine with Illumina in September 2020, Grail had not quantified the efficiencies that could result from the combination. (Freidin (Grail) Tr. 3141).

5070. Grail's FP&A team, which Mr. Freidin leads, did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145).

5071. Grail's Medical Affairs and Regulatory teams did not conduct an analysis of the extent of any acceleration to FDA approval that might occur if Grail were acquired by Illumina. (Freidin (Grail) Tr. 3145).

5072. [redacted] (Ofman (Grail) Tr. 3379 (*in camera*)).

5073. [redacted] (Ofman (Grail) Tr. 3379-80 (*in camera*)).

5074. Grail's former CEO, Hans Bishop, could not quantify at trial how much sooner he expected Grail to receive PMA approval with assistance from Illumina versus without. (Bishop (Grail) Tr. 1426); PX7083 (Bishop (Grail) Dep. at 83-85)).

5075. Respondents' expert, Dr. Carlton, testified that he is "not the source" for the opinion that Illumina can accelerate the process for Galleri to achieve FDA approval. (RX6000 (Carlton Trial Dep. at 96-97); PX7134 (Carlton Dep. at 191)).

5076. Dr. Carlton did not offer any testimony as an expert on the FDA's regulatory process. (RX6000 (Carlton Trial Dep. at 97); PX7134 (Carlton Dep. at 14)).

5077. Dr. Carlton relied on Illumina's estimates for FDA acceleration of Galleri. (PX7134 (Carlton Dep. at 191)).

5078. Dr. Carlton did not perform a detailed analysis of what specific capabilities Illumina thinks it can contribute to accelerate FDA approval for Galleri. (RX6000 (Carlton Trial Dep. at 97)).

5079. {[redacted]} (PX7134 (Carlton Dep. at 197-198) (*in camera*)).

5080. [redacted] PX7134 (Carlton Dep. at 198) (*in camera*)).

(b) Illumina and Grail Have Not Identified Specific Steps Toward FDA Approval That Illumina Might Accelerate

5081. [redacted]} (PX6056 (Illumina) at 094 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

5082. [redacted] (PX6056 (Illumina) at 094 (Illumina, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

5083. [redacted]} (Febbo (Illumina) Tr. 4430 (*in camera*)).

5084. [redacted] (Febbo (Illumina) Tr. 4429-30 (*in camera*)).

5085. {[redacted]} (Febbo (Illumina) Tr. 4429-30 (*in camera*); (Qadan (Illumina) Tr. 4239 (*in camera*)).

5086. {[redacted]} (Febbo (Illumina) Tr. 4429-30 (*in camera*)).

5087. [redacted] (Qadan (Illumina) Tr. 4239 (*in camera*)).

5088. [redacted]} (Febbo (Illumina) Tr. 4430 (*in camera*)).

5089. Illumina's CEO, Francis deSouza made a presentation to Grail's board on September 14, 2020. (Freidin (Grail) Tr. 3146-47).

5090. Grail did not learn from Mr. deSouza's presentation what Illumina's plans were for how to help GRAIL with FDA approvals. (Freidin (Grail) Tr. 3147).

5091. [redacted] (Ofman (Grail) Tr. 3381 (*in camera*)).

5092. [redacted] (Ofman (Grail) Tr. 3382 (*in camera*)).

5093. [redacted] (Qadan (Illumina) Tr. 4240-41 (*in camera*)).

5094. Dr. Febbo testified at trial that Illumina will not be able to "work together [with Grail] and find those specific areas where we can help them accelerate" Galleri's FDA approval until Illumina and Grail are combined. (Febbo (Illumina) Tr. 4344-45).

(c) Illumina and Grail Have Not Engaged in Integration Planning Related to FDA Acceleration

5095. Integration planning between Illumina and Grail has not started. (Bishop (Grail) Tr. 1425; Freidin (Grail) Tr. 3153-54).

5096. Grail's CEO, Hans Bishop, testified in his investigational hearing that integration planning has "yet to kick off in any meaningful way." (PX7069 (Bishop (Grail) IHT at 42)).

5097. At trial, Mr. Bishop testified that he could not answer how many employees Illumina plans on deploying to assist with the Illumina PMA "because to answer such a question, integration planning would have to be under way . . . and integration planning hasn't started." (Bishop (Grail) Tr. 1425).

5098. Between March 22, 2021 and June 23, 2021, Illumina and Grail did not have any discussions regarding integration. (Freidin (Grail) Tr. 3153-54).

5099. Besides financial reporting, no other integration has taken place since the close of the transaction. (Freidin (Grail) Tr. 3154).

5100. A meeting between the Illumina and Grail R&D, regulatory, medical affairs and government affairs teams never happened. (Freidin (Grail) Tr. 3156).

5101. Grail's FDA lead, Deepshikha Bhandari, and her counterpart at Illumina never met. (Freidin (Grail) Tr. 3156-57).

5102. Illumina's clinical affairs team is not currently collaborating with Grail's clinical affairs team. (Freidin (Grail) Tr. 3157).

5103. Illumina's regulatory affairs team is not currently collaborating with Grail's regulatory affairs team. (Freidin (Grail) Tr. 3157).

5104. A planned meeting between Illumina and Grail's commercial teams never happened. (Freidin (Grail) Tr. 3156).

5105. A planned meeting between the Illumina and Grail lab operations teams never happened. (Freidin (Grail) Tr. 3156).

5106. Integration meetings to define where Illumina could accelerate Grail's objectives have not happened. (PX7108 (Freidin (Grail) Dep. at 283)).

5107. Mr. Bishop testified that he does not know how many Illumina employees will work on Grail's PMA submissions to the FDA. (Bishop (Grail) Tr. 1424-25).

5108. No one at Illumina has communicated to Mr. Bishop how many employees Illumina plans on deploying to assist with Galleri's PMA. (Bishop (Grail) Tr. 1425).

5109. Grail does not know whether Illumina is planning to transfer employees to Grail. (PX7066 (Freidin (Grail) IHT at 258)).

5110. Any changes to Grail's post-acquisition organizational structure have not been determined yet. (PX7066 (Freidin (Grail) IHT at 257)).

5111. Francis deSouza does not get involved in the details of the FDA submissions. (deSouza (Illumina) Tr. 2418).

5112. Francis deSouza did not look through the resumes of the Grail employees and, accordingly, is unfamiliar with their expertise. (deSouza (Illumina) Tr. 2419).

5113. [redacted] (Freidin (Grail) Tr. 3110 (*in camera*)); PX7066 (Freidin (Grail) IHT at 268-269).

5114. [redacted] } (Ofman (Grail) Tr. 3380 (*in camera*)).

5115. [redacted] } (Ofman (Grail) Tr. 3380 (*in camera*)).

5116. According to Phil Febbo, Illumina's Chief Medical Officer, Illumina will not be able to "work together [with Grail] and find those specific areas where [Illumina] can help [Grail] accelerate" until Illumina and Grail are combined. (Febbo (Illumina) Tr. 4344-45).

5117. [redacted]

[redacted]} (Ofman (Grail) Tr. 3380-81 (*in camera*)).

5118. [redacted]} (Ofman (Grail) Tr. 3381-82 (*in camera*)).

5119. Mr. Freidin is Grail's point person for integration with Illumina. (Freidin (Grail) Tr. 3138).

5120. Mr. Freidin asked to see Illumina's deal model. (Freidin (Grail) Tr. 3138-39).

5121. Illumina did not make its deal model available to Mr. Freidin. (Freidin (Grail) Tr. 3139).

5122. Illumina did not ask Mr. Freidin to review its deal model to stress test it. (Freidin (Grail) Tr. 3139).

5123. At trial, Mr. Freidin testified that he has not seen Illumina's financial model for the Illumina-Grail deal. (Freidin (Grail) Tr. 3139).

5124. [redacted]} (PX4096 (Grail) at 009 (Email from A. Freidin, Grail, to H. Bishop, Grail, M.L. Song, Grail, M. Young, Grail, Oct. 24, 2020, attaching "Grail Integration Planning and Pre-Closing Activities," Oct. 23, 2020) (*in camera*); PX7066 (Freidin (Grail) IHT at 277-278)).

5125. [redacted] (PX7066 (Freidin (Grail) IHT at 280); PX4096 (Grail) at 014 (Email from A. Freidin, Grail, to H. Bishop, Grail, M.L. Song, Grail, M. Young, Grail, Oct. 24, 2020, attaching "Grail Integration Planning and Pre-Closing Activities," Oct. 23, 2020) (*in camera*)).

5126. {[redacted]} (PX4222 (Grail) at 001, 009 (Grail, Email from C. Cotter, Grail, to A. Freidin, Grail, Paul Scagnetti, Illumina, Mar. 15, 2021, attaching "Preparing for Day 1," Mar 15, 2021) (*in camera*)).

(d) Illumina and Grail Do Not Address the Costs Associated with Attempting to Accelerate FDA Approval

5127. Under the Horizontal Merger Guidelines, "[c]ognizable efficiencies are assessed net of costs produced by the merger or incurred in achieving those efficiencies." (Horizontal Merger Guidelines § 10; *see also* PX6092 (Rothman Rebuttal Report) ¶ 39).

5128. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 21 (RFA No. 28) (*in camera*)).

5129. [redacted] (RX3867 (Deverka Rebuttal Report) ¶ 147 (*in camera*); PX7084 (Qadan (Illumina) Dep. at 183-85) ([redacted]) (*in camera*)).

5130. [redacted] (PX7140 (Rothman Trial Dep. at 27) (*in camera*); *see also* PX6092 (Rothman Rebuttal Report) ¶¶ 29-30 (*in camera*)).

5131. [redacted] (PX7140 (Rothman Trial Dep. at 27) (*in camera*); *see also* PX6092 (Rothman Rebuttal Report) ¶ 30 (*in camera*)).

5132. Dr. Deverka testified that if Illumina's acquisition of Grail results in de-prioritization of projects due to a constraint on Illumina's employees' ability to work both on Illumina and Grail projects, Illumina could need to hire additional personnel to work on the projects. (PX7130 (Deverka Dep. at 173-174)).

5133. [redacted] (Ofman (Grail) Tr. 3382 (*in camera*)).

5134. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 29 (*in camera*)).

5135. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 30 (*in camera*)).

(e) FDA Approval of MCED Tests Requires a PMA Supported by Clinical Trials

5136. {[redacted]} (PX6056 (Illumina Narrative Response to Second Request) at 015 (Spec. No. 2(c) (quoting www.fda.gov/medical-devices/premarket-submissions/premarket-approvalpma)).

5137. Grail's Galleri test is a Class III diagnostic test that will require Premarket Approval from the FDA. (Febbo (Illumina) Tr. 4445).

5138. [redacted] (Febbo (Illumina) Tr. 4335 (*in camera*)).

5139. MCED test developers must conduct clinical trials for their tests to obtain regulatory approval. (Della Porta (Grail) Tr. 584).

5140. [redacted] (Rabinowitz (Natera) Tr. 394-95 (*in camera*)).

5141. [redacted]} (Rabinowitz (Natera) Tr. 395 (*in camera*)).

5142. "Illumina admits that the FDA has never granted a PMA for an NGS-based early cancer screening test." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 007 (RFA No. 2); *see also* Freidin (Grail) Tr. 3106).

5143. "Illumina admits that the FDA has never granted a PMA for an NGS-based liquid biopsy test for early cancer screening in asymptomatic individuals." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 007 (RFA No. 3)).

5144. Grail's S-1 states that the "FDA has never granted marketing authorization for a multi-cancer detection test." (PX4082 (Grail) at 047 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, Morgan Stanley, et al., attaching "Amendment No. 1 to Form S-1 Registration Statement," Sept. 2020)).

5145. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 18 (*in camera*)).

(f) Illumina Has Limited Relevant Experience Obtaining FDA PMA Approvals

5146. The only Class III NGS-based diagnostic test for which Illumina has obtained Premarket Approval from the FDA is the Praxis therapy selection test. (Febbo (Illumina) Tr. 4445-46).

5147. Illumina's Praxis test identifies coding mutations in the RAS gene family that, if present, indicate that the patient would not benefit from Vectibix. (Febbo (Illumina) Tr. 4446).

5148. Illumina's Praxis test sequences tumor tissue samples. (Febbo (Illumina) Tr. 4446).

5149. Illumina's Praxis test is not a liquid biopsy test. (Febbo (Illumina) Tr. 4446).

5150. Illumina's Praxis test does not assay cell-free DNA from blood. (Febbo (Illumina) Tr. 4446).

5151. Illumina's Praxis test is indicated for people with metastatic colon cancer. (Febbo (Illumina) Tr. 4446).

5152. Illumina's Praxis test does not screen healthy people for cancer. (Febbo (Illumina) Tr. 4446).

5153. [redacted] (Bishop (Grail) Tr. 1424; Freidin (Grail) Tr. 3106 (*in camera*)).

5154. Illumina has never engaged with the FDA regarding an MCED test. (Febbo (Illumina) Tr. 4451).

5155. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 17 (*in camera*)).

5156. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 16 (*in camera*)).

5157. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 014 (RFA No. 14) (*in camera*); *see also* Febbo (Illumina) Tr. 4429 (*in camera*)).

5158. Illumina has never sponsored any clinical study that the FDA has relied on to grant a PMA to a Class III diagnostic test. (Febbo (Illumina) Tr. 4448).

5159. Illumina's Praxis test received its PMA from the FDA before Illumina's current Chief Medical Officer, Dr. Phillip Febbo, joined the company in 2018. (Febbo (Illumina) Tr. 4447, 4451).

5160. Since Dr. Febbo, Illumina's Chief Medical Officer, joined the company in 2018, Illumina has not obtained a PMA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4450-51).

5161. Since Dr. Febbo joined the company in 2018, Illumina has not submitted a final PMA application to the FDA for any NGS-based diagnostic test. (Febbo (Illumina) Tr. 4451).

5162. [redacted] (Febbo (Illumina) Tr. 4429 (*in camera*)).

5163. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 25 (*in camera*)).

5164. {[redacted]} (Freidin (Grail) Tr. 3113 (*in camera*)).

5165. {[redacted]} (Freidin (Grail) Tr. 3113 (*in camera*)).

5166. {[redacted]} (Freidin (Grail) Tr. 3115 (*in camera*)).

(i) Illumina's Praxis Therapy Selection Test Was Approved on the Basis of a Third Party's Clinical Study

5167. Illumina's Praxis therapy selection test is a companion diagnostic test for the drug Vectibix. (Febbo (Illumina) Tr. 4446).

5168. Illumina's PMA application for the Praxis test relied upon the PRIME clinical study. (Febbo (Illumina) Tr. 4448).

5169. Amgen sponsored the PRIME clinical study, not Illumina. (Febbo (Illumina) Tr. 4448; PX0388, ClinicalTrials.gov, PRIME: Panitumumab Randomized Trial in Combination with Chemotherapy for Metastatic Colorectal Cancer to Determine Efficacy (ClinicalTrials.gov Identifier: NCT00364013), https://clinicaltrials.gov/ct2/show/record/NCT00364013?term=PRIME&spons=Amgen&draw=2&rank=2 (last visited Sept. 23, 2021) (listing Amgen as the sole "sponsor" for the PRIME study)).

5170. Amgen is listed as the sole "responsible party" on ClinicalTrials.gov for the PRIME study validating the safety and effectiveness of Praxis. PX0388, ClinicalTrials.gov, PRIME: Panitumumab Randomized Trial in Combination with Chemotherapy for Metastatic

Colorectal Cancer to Determine Efficacy (ClinicalTrials.gov Identifier: NCT00364013), https://clinicaltrials.gov/ct2/show/record/NCT00364013?term=PRIME&spons=Amgen&draw=2&rank=2 (last visited Sept. 23, 2021)).

5171. The PRIME study was the only clinical study Illumina submitted to the FDA as part of the Praxis PMA application. (Febbo (Illumina) Tr. 4448; PX0392 at 028-30 (FDA, Summary of Safety and Effectiveness Data, Praxis™ Extended RAS Panel, June 29, 2017) (describing a single study).

5172. Illumina is not listed as either a sponsor or collaborator for the PRIME study on ClinicalTrials.gov. PX0391, ClinicalTrials.gov Search Results for "Illumina," (last visited Sept. 23, 2021)).

(ii) [redacted]

5173. [redacted] (PX7099 (Febbo (Illumina) Dep. at 88-89) (*in camera*)).

5174. [redacted] (Febbo (Illumina) Tr. 4381 (*in camera*)).

5175. [redacted] (Febbo (Illumina) Tr. 4381 (*in camera*)).

5176. [redacted] (Febbo (Illumina) Tr. 4405 (*in camera*)).

5177. "Illumina admits that the FDA has not granted a PMA for Illumina's NIPT in vitro diagnostic test, including because Illumina has not completed submission of its PMA for its NIPT in vitro diagnostic test." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 13 (RFA No. 12)).

5178. [redacted] (Febbo (Illumina) Tr. 4381 (*in camera*)).

5179. [redacted] (Febbo (Illumina) Tr. 4381-82 (*in camera*)).

5180. [redacted] (Febbo (Illumina) Tr. 4382 (*in camera*)).

5181. [redacted] (Febbo (Illumina) Tr. 4383 (*in camera*)).

5182. {[redacted]} (Febbo (Illumina) Tr. 4383 (*in camera*)).

5183. [redacted] } (Febbo (Illumina) Tr. 4383 (*in camera*).

5184. [redacted] (Febbo (Illumina) Tr. 4406 (*in camera*)).

5185. [redacted] (Febbo (Illumina) Tr. 4406 (*in camera*)).

5186. [redacted] (PX2587 (Illumina) at 006 [redacted] (*in camera*)).

5187. [redacted] } (Febbo (Illumina) Tr. 4383-84, 4406 (*in camera*)).

5188. [redacted] } (Febbo (Illumina) Tr. 4383-84, 4406-07 (*in camera*)).

5189. [redacted] (Febbo (Illumina) Tr. 4407-08 (*in camera*)).

5190. [redacted] } (Febbo (Illumina) Tr. 4410 (*in camera*)).

5191. [redacted] (Febbo (Illumina) Tr. 4410-11 (*in camera*)).

5192. [redacted] (Febbo (Illumina) Tr. 4411 (*in camera*)).

5193. [redacted] } (Febbo (Illumina) Tr. 4410 (*in camera*)).

5194. [redacted] (Febbo (Illumina) Tr. 4410 (*in camera*)).

5195. [redacted] (Febbo (Illumina) Tr. 4408 (*in camera*)).

5196. [redacted] (Febbo (Illumina) Tr. 4409 (*in camera*)).

5197. [redacted] } (Febbo (Illumina) Tr. 4411 (*in camera*)).

5198. [redacted] } (PX2585 (Illumina) at 002 (*in camera*)).

5199. [redacted] } (PX2585 (Illumina) at 002 (*in camera*)).

5200. { [redacted] } (Febbo (Illumina) Tr. 4409) (*in camera*).

5201. [redacted] } (Febbo (Illumina) Tr. 4411 (*in camera*)).

5202. [redacted] } (Febbo (Illumina) Tr. 4411-4412 (*in camera*)).

5203. [redacted] (PX2584 (Illumina) at 001 (*in camera*)).

5204. [redacted] } (PX2584 (Illumina) at 001 (*in camera*)).

5205. [redacted] (Febbo (Illumina) Tr. 4416-4417 (*in camera*)).

5206. [redacted] } (Febbo (Illumina) Tr. 4417 (*in camera*)).

5207. [redacted] } (Febbo (Illumina) Tr. 4417 (*in camera*)).

5208. [redacted] } (PX2590 (Illumina) at 001-02 (Email from K. Davy, Illumina, to J. Godsey and P. Febbo, Illumina, Nov. 19, 2020) (*in camera*)).

5209. [redacted] (PX2590 (Illumina) at 001 (Email from K. Davy, Illumina, to J. Godsey and P. Febbo, Illumina, Nov. 19, 2020) (*in camera*)).

5210. [redacted] } (Febbo (Illumina) Tr. 4418 (*in camera*)).

5211. [redacted] (PX2590 (Illumina) at 001 (Email from K. Davy, Illumina, to J. Godsey and P. Febbo, Illumina, Nov. 19, 2020) (*in camera*)).

5212. [redacted] } (Febbo (Illumina) Tr. 4419-20 (*in camera*)).

5213. [redacted] } (Febbo (Illumina) Tr. 4420-21 (*in camera*)).

5214. [redacted] (PX2591 (Illumina) at 001 (Email from P. Febbo, Illumina, to K. Gutekunst, Illumina, Dec. 3, 2020) (*in camera*)). [redacted} (Febbo (Illumina) Tr. 4421-22 (*in camera*)).

5215. [redacted} (Febbo (Illumina) Tr. 4414-15 (*in camera*)).

5216. [redacted] (Febbo (Illumina) Tr. 4415-16 (*in camera*)).

5217. [redacted] (PX2587 (Illumina) at 001-02 [redacted] (*in camera*)).

5218. [redacted] (PX2587 (Illumina) at 006 [redacted] (*in camera*)).

5219. [redacted] (PX2587 (Illumina) at 006 [redacted] (*in camera*)).

5220. [redacted} (PX2587 (Illumina) at 020 [redacted]

[redacted] (*in camera*)).

5221. [redacted] (Febbo (Illumina) Tr. 4416 (*in camera*)).

5222. [redacted] (Febbo (Illumina) Tr. 4416 (*in camera*)).

(iii) {[redacted]}

5223. [redacted] } (Febbo (Illumina) Tr. 4422 (*in camera*)).

5224. [redacted] } (Febbo (Illumina) Tr. 4422 (*in camera*)).

5225. [redacted] (Febbo (Illumina) Tr. 4422-23 (*in camera*)).

5226. [redacted] } (Febbo (Illumina) Tr. 4389, 4423 (*in camera*)).

5227. [redacted] } (Febbo (Illumina) Tr. 4423 (*in camera*)).

5228. [redacted] (Febbo (Illumina) Tr. 4423 (*in camera*)).

5229. "Illumina admits that the FDA has not granted a PMA for Illumina's TSO Comp, including because Illumina has not completed submission of its PMA for its TSO Comp." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 13-14 (RFA No. 13)).

5230. {[redacted]} (Febbo (Illumina) Tr. 4390 (*in camera*)).

5231. {[redacted]} (Febbo (Illumina) Tr. 4389 (*in camera*)).

5232. {[redacted]} (Febbo (Illumina) Tr. 4390 (*in camera*)).

5233. {[redacted]} (Febbo (Illumina) Tr. 4390 (*in camera*)).

5234. {[redacted]} (Febbo (Illumina) Tr. 4390 (*in camera*)).

5235. [redacted]} (PX2593 (Illumina) at 002-14 (Letter from R. Philip, FDA, to J. Fleming, Illumina, Jan. 21, 2021) (*in camera*)).

5236. [redacted] (Febbo (Illumina) Tr. 4391 (*in camera*)).

5237. [redacted]} (PX2593 (Illumina) at 002-14 (Letter from R. Philip, FDA, to J. Fleming, Illumina, Jan. 21, 2021) (*in camera*)).

5238. [redacted]} (Febbo (Illumina) Tr. 4426 (*in camera*)).

5239. [redacted]} (PX2593 (Illumina) at 002-14 (Letter from R. Philip, FDA, to J. Fleming, Illumina, Jan. 21, 2021) (*in camera*)).

5240. [redacted] (PX2593 (Illumina) at 001 (Email from J. Fleming, Illumina, to K. Gutekunst, Illumina, and J. McMullen, Illumina, Jan. 22, 2021) (*in camera*)).

5241. [redacted]} (PX2593 (Illumina) at 001 (Email from K. Gutekunst, Illumina, to P. Febbo, Illumina, Jan. 22, 2021) (*in camera*)).

5242. [redacted] (Febbo (Illumina) Tr. 4427-28 (*in camera*)).

5243. [redacted] (Febbo (Illumina) Tr. 4426-27 (*in camera*)).

5244. [redacted] (Febbo (Illumina) Tr. 4423-24 (*in camera*)).

5245. [redacted] (Febbo (Illumina) Tr. 4425-26 (*in camera*)).

5246. [redacted] (Febbo (Illumina) Tr. 4428 (*in camera*)).

5247. [redacted] (Febbo (Illumina) Tr. 4429 (*in camera*)).

5248. [redacted] (PX2582 (Illumina) at 001 (Email from J. Godsey, Illumina, to S. Tousi, K. Reeves, J. Goswami, R. Ragusa, and P. Febbo, Illumina, Apr. 14, 2021) (*in camera*)).

5249. [redacted] (Febbo (Illumina) Tr. 4423 (*in camera*)).

(g) If Illumina Could Meaningfully Accelerate Galleri, It Has the Incentive to Do So Absent the Merger

5250. [redacted] (PX7138 (Scott Morton Trial Dep. at 54-55) (*in camera*)).

5251. Dr. Alex Aravanis, Illumina's Chief Technology Officer, testified that Illumina has an incentive to accelerate the adoption of sequencing-based cancer screening tests even absent an acquisition of Grail. (PX7065 (Aravanis (Illumina) IHT at 225-226)).

5252. {[redacted]} (PX7140 (Rothman Trial Dep. at 21-22) (*in camera*)).

5253. [redacted]} (PX6090 (Scott Morton Report) ¶¶ 238-39 (*in camera*)).

5254. [redacted]} (PX6090 (Scott Morton Report) ¶ 239 (*in camera*)).

5255. [redacted] (PX6090 (Scott Morton Report) ¶ 239 (*in camera*)).

5256. [redacted]} (PX6090 (Scott Morton Report) ¶ 239 (*in camera*)).

5257. {[redacted]

[redacted]}

(PX6090 (Scott Morton Report) ¶ 240 (*in camera*)).

5258. {[redacted]} (PX6092 (Rothman Rebuttal Report) ¶ 84 (*in camera*)).

(h) Grail Is Already Pursuing FDA Approval Aggressively as an Independent Company

5259. {[redacted]} (Bishop (Grail) Tr. 1345; PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*) ([redacted]).

5260. [redacted]} (Bishop (Grail) Tr. 1345; PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021 (*in camera*) ({[redacted]).

5261. [redacted] (Ofman (Grail) Tr. 3351 (*in camera*); *see* PX7069 (Bishop (Grail) IHT at 193-34); PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); *see also* Febbo (Illumina) Tr. 4430 (*in camera*) ([redacted]); PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

5262. [redacted] (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

5263. [redacted] (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

5264. [redacted] (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

5265. [redacted] (Ofman (Grail) Tr. 3351 (*in camera*)).

5266. [redacted]

[redacted] (PX6092 (Rothman Rebuttal Report) ¶ 53 (*in camera*)).

5267. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 28 (*in camera*)).

5268. [redacted] (Ofman (Grail) Tr. 3384 (*in camera*)).

5269. [redacted] (PX6069 (Illumina) at 016-17 (Illumina Responses & Objections to FTC Requests for Admissions) (*in camera*)).

5270. [redacted] (Ofman (Grail) Tr. 3384-85 (*in camera*)).

(i) [redacted]

5271. [redacted] (Bishop (Grail) Tr. 1437) (*in camera*)).

5272. [redacted] (Bishop (Grail) Tr. 1437-38) (*in camera*)).

5273. [redacted] (Bishop (Grail) Tr. 1438) (*in camera*)).

5274. [redacted] (Bishop (Grail) Tr. 1441) (*in camera*)).

5275. [redacted] (Bishop (Grail) Tr. 1442-43 (*in camera*); PX7083 (Bishop (Grail) Dep. at 145) (*in camera*); PX5044 (Grail) at 003 (LRP Review, Aug. 20, 2020) (*in camera*)).

5276. [redacted] (Bishop (Grail) Tr. 1449) (*in camera*)).

5277. [redacted] (Bishop (Grail) Tr. 1449-50) (*in camera*)).

5278. [redacted] } ((Bishop (Grail) Tr. 1452) (*in camera*); PX5046 (Grail) at 007 [redacted] (*in camera*)).

5279. According to Mr. Bishop, FDA approval "will likely be a prerequisite for getting broad-based reimbursement." (PX7069 (Bishop (Grail) IHT at 94-95)).

5280. [redacted] } (Freidin (Grail) Tr. 3171 (*in camera*)).

(ii) [redacted]

5281. [redacted] } (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

5282. { [redacted] } (Bishop (Grail) Tr. 1466-68 (*in camera*)).

5283. [redacted] } (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

5284. [redacted] } (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)). { [redacted] } (PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

5285. [redacted] } (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)). { [redacted] } (PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

5286. [redacted] (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)). [redacted] } (Bishop (Grail) Tr. 1466-

68 (*in camera*); PX4489 (Grail) at 011 (Email from H. Bishop, Grail, to Grail-BOD et al., Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

5287. In its August 2020 testing-the-waters meetings for a potential IPO, Grail identified "CCGA3 clinical results validating Galleri" as a "key milestone" expected in the first half of 2021. (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD et al, Grail, Aug. 20, 2020)). Dr. Ofman testified that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3442).

5288. In its August 2020 testing-the-waters meetings for a potential IPO, Grail identified "PATHFINDER results" as a "key milestone" expected in the first half of 2021. (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD et al, Grail, Aug. 20, 2020)). Dr. Ofman testified at trial that Grail achieved that milestone by presenting PATHFINDER results at ASCO. (Ofman (Grail) Tr. 3442). The interim results for PATHFINDER were presented at ASCO in the first half of 2021. (RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021)).

5289. In its August 2020 testing-the-waters meetings for a potential IPO, Grail identified "Channel & regional partner announcements" as a "key milestone" expected in 2020-2021. (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD et al, Grail, Aug. 20, 2020)). Dr. Ofman testified at trial that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3444).

5290. In its August 2020 testing-the-waters meetings for a potential IPO, Grail identified "Multi-cancer laboratory developed test (LDT) launch" as a "key milestone" expected in 2021. (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD et al, Grail, Aug. 20, 2020)). Dr. Ofman testified at trial that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3444).

(iii) Grail Has a Well-Established Regulatory Team

5291. {[redacted]} (Freidin (Grail) Tr. 3108 (*in camera*)).

5292. Dr. Ofman has worked on bringing technology to patients for about 25 years. (Ofman (Grail) Tr. 3449).

5293. There is a group of Grail employees already working to obtain a PMA for Galleri. (Bishop (Grail) Tr. 1345).

5294. [redacted] (PX4615 (Grail) at 064 [redacted] (*in camera*)).

5295. [redacted] (PX4615 (Grail) at 068 [redacted] (*in camera*)).

(iv) Grail Launched the Largest Clinical Study Program of Its Kind Without Illumina

5296. [redacted] (PX7092 (Ofman (Grail) Dep. at 266-67) (*in camera*)).

5297. [redacted] (Ofman (Grail) Tr. 3323-24 (*in camera*)).

5298. Dr. Ofman 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).

5299. Grail describes its clinical study program as "one of the largest clinical study programs ever conducted in genomic medicine." (RX0694 (Grail) at 002 (Email from J. Ofman, Grail, to M. Burns and K. Grossman, Grail, attaching "Grail Announces Validation of Its Multi-Cancer Early Detection Test Published in Annals of Oncology," Apr. 13, 2020)).

5300. Grail's Form S-1 states that Grail has "invested significant capital and resources in [its] foundational studies, which have collectively enrolled approximately 115,000 participants, to build what we believe are the largest linked datasets of genomic and clinical data in the cancer field." (PX4082 (Grail) at 008 (Email attaching Grail 2020 S-1/Amended, Sept. 2020); PX7069 (Bishop (Grail) IHT at 191-92 (testifying that Grail has built the largest linked datasets of genomic and clinical data in the cancer field)).

5301. As Grail explained in its S-1 filing, many companies do not have "the financial resources to invest in population-scale clinical trials and rigorous analytics to compete with [Grail's] products." (PX4082 (Grail) at 128 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

5302. Grail has directly enrolled more than ten times the number of patients that Illumina has directly enrolled in clinical studies. (Febbo (Illumina) Tr. 4449).

5303. [redacted] (Bishop (Grail) Tr. 1481 (*in camera*)).

5304. Grail designed its clinical study program as an independent company. (Qadan (Illumina) Tr. 4261).

5305. Grail launched its clinical study program as an independent company. (Qadan (Illumina) Tr. 4261).

5306. {[redacted]} (Ofman (Grail) Tr. 3307; PX7092 (Ofman (Grail) Dep. at 187) (*in camera*)).

5307. Grail conducted its CCGA study as an independent company. (Qadan (Illumina) Tr. 4261).

5308. {[redacted]} (PX5044 (Grail) at 027 (LRP Review, Aug. 20, 2020) (*in camera*)).

5309. Grail has directly enrolled over 130,000 participants in clinical studies. (PX0390 ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021).

5310. The largest number of participants that Illumina has directly enrolled in a clinical study is three thousand participants. (Febbo (Illumina) Tr. 4450; PX0391 (ClinicalTrials.gov Search Results for "Illumina," Sept. 23, 2021)).

5311. Grail has directly enrolled more than ten times the number of participants that Illumina has directly enrolled in clinical studies. (Febbo (Illumina) Tr. 4449).

5312. Grail has directly enrolled more than 30 times the number of participants in a single clinical study that Illumina has directly enrolled in a single clinical study. (Febbo (Illumina) Tr. 4450; PX0390 ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021; PX0391 (ClinicalTrials.gov Search Results for "Illumina," Sept. 23, 2021)).

5313. Illumina's largest prospective clinical study relates to its Denali program. (Febbo (Illumina) Tr. 4449-50). Illumina has directly enrolled two to three thousand participants in its Denali-related study. (Febbo (Illumina) Tr. 4450).

5314. Grail's proven ability to partner with other institutions shows they have the ability to generate clinical utility data. (Qadan (Illumina) Tr. 4261-63).

5315. Grail has completed one clinical study for the Galleri test and has three more clinical studies ongoing for Galleri. (PX7069 (Bishop (Grail) IHT at 79); PX4082 (Grail) at 124-27 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, Morgan Stanely, attaching Grail 2020 S-1/Amended, Sept. 2020); PX0086 (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)).

5316. Grail has the STRIVE, SUMMIT, PATHFINDER, and U.K. NHS studies ongoing at various stages. (Ofman (Grail) Tr. 3293-94).

5317. Dr. Ofman explained that Grail undertook the SUMMIT and STRIVE studies because, after the CCGA study, "we needed to also study our assay in what we call the intended use population." (Ofman (Grail) Tr. 3294-95).

5318. STRIVE and SUMMIT are "two very large cohort studies" that are "noninterventional." The two cohorts are women getting mammograms and men and women getting low-dose CT for high-risk lung cancer screening. (Ofman (Grail) Tr. 3293).

5319. {[redacted]} (PX0086 at 002 ("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); PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

5320. Grail designed and enrolled patients in its Strive study. (Qadan (Illumina) Tr. 4262).

5321. [redacted] (Febbo (Illumina) Tr. 4450; PX0390 (ClinicalTrials.gov Search Results for "Grail," Sept. 23, 2021); PX4430 (Grail) at 021 [redacted] (*in camera*)).

5322. [redacted] (PX6093 (Navathe Rebuttal Report) at Table 2 (*in camera*); RX3134 (National Institutes of Health, U.S. National Library of Medicine, The STRIVE Study: Development of a Blood Test for Early Detection of Multiple Cancer Types, https://clinicaltrials.gov/ct2/show/NCT03085888) (last visited Jan. 3, 2022)).

5323. Grail partnered with the Mayo Institute in connection with the Strive study. (Qadan (Illumina) Tr. 4262).

5324. Grail partnered with the Cleveland Clinical in connection with the Strive study. (Qadan (Illumina) Tr. 4262-63).

5325. Grail partnered with the Henry Ford Health System in connection with the Strive study. (Qadan (Illumina) Tr. 4262-63).

5326. Grail partnered with the Dana-Farber Cancer Institute in connection with the Strive study. (Qadan (Illumina) Tr. 4262-63).

5327. Grail designed and enrolled patients in its Pathfinder study. (Qadan (Illumina) Tr. 4262).

5328. PATHFINDER is "an interventional study, which is what we call a real-world clinical practice study" of 6,600 screening eligible population with no suspicion of cancer. (Ofman (Grail) Tr. 3293).

5329. According to Dr. Ofman, Grail felt that PATHFINDER, "which was an actual return of results study, interventional, in actual clinical practice, would be a more powerful way to add to our clinical validation than [STRIVE and SUMMIT]." (Ofman (Grail) Tr. 3296).

5330. As part of PATHFINDER, patients received results from their test and were tracked for one year. (Ofman (Grail) Tr. 3293).

5331. [redacted] (Ofman (Grail) Tr. 3330 (*in camera*)).

5332. [redacted] (Ofman (Grail) Tr. 3330 (*in camera*)).

5333. [redacted] (Ofman (Grail) Tr. 3293-94; PX7092 (Ofman (Grail) Dep. at 123); RX3523 (NHS) at 002 ("NHS to pilot potentially revolutionary blood test that detects more than 50 cancers," Nov. 27, 2020); PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*))).

5334. [redacted] (Ofman (Grail) Tr. 3293-94; PX7092 (Ofman (Grail) Dep. at 123); RX3523 at 2 ("NHS to pilot potentially revolutionary blood test that detects more than 50 cancers," Nov. 27, 2020);PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

5335. At trial, Dr. Ofman summarized the U.K. study protocol: "It's 140,000 screening-eligible individuals randomized to getting Galleri or not getting Galleri along with standard of care screening, and we'll be following patients for three consecutive years." (Ofman (Grail) Tr. 3293-94).

5336. The U.K. study is the largest trial for any cancer screening test ever. (Freidin (Grail) Tr. 3162).

5337. Grail signed the agreement for the U.K.-based trial in December 2020. (Freidin (Grail) Tr. 3161).

5338. Grail negotiated its agreement with NHS before Illumina acquired Grail. (Freidin (Grail) Tr. 3161).

5339. Grail's international operations include 10-20 people in the United Kingdom to facilitate the NHS study. (Freidin (Grail) Tr. 3008).

5340. Grail is currently enrolling patients in its real-world evidence study in the United Kingdom. (Qadan (Illumina) Tr. 4263).

5341. The U.K. NHS study launched in September 2021 and is the "largest, real-world, what we call a pragmatic, randomized clinical trial" ever in genomics. (Ofman (Grail) Tr. 3293-94; Freidin (Grail) Tr. 3008, 3161).

(v) Grail Has Met Regularly with the FDA

5342. {[redacted]} (PX4615 (Grail) at 070 [redacted] (*in camera*)).

5343. Grail's Form S-1 explains the status of Grail's conversations with the FDA as follows:

> We are engaged in ongoing discussions with FDA regarding the data that will be needed to support a successful PMA for a multi-cancer test for our planned indications, including whether we would need to provide additional analyses and information beyond that which we are currently planning to produce based on the designs of our current and planned clinical studies.

(PX4082 (Grail) at 047 (Email from J. Ofman, Grail, to R. Klausner, Grail, June 6, 2020 (*in camera*)).

5344. [redacted]

5345. {[redacted]

5346. [redacted]

[redacted]

5347. {[redacted]} (PX4323 (Grail) at 001, Email from Deepshikha Bhandari, Grail, to Grail executive team, Dec. 28, 2020) (*in camera*)).

(vi) {[redacted]

5348. [redacted]} (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email attaching Grail BoD 2021 Budget, Dec. 2020) (*in camera*)).

5349. [redacted]} (Bishop (Grail) Tr. 1468 (*in camera*); PX4489 (Grail) at 011 (Email from S. Green, Grail, to Grail Board of Directors, attaching Grail BoD 2021 Budget, December 9, 2020, (*in camera*)).

5350. {[redacted] (PX4213 (Grail) at 009 (Email and Presentation from A. Freidin, Grail, to C. Friedman, M. Ho, B. Rastetter, Grail, Dec. 3, 2020)).

(vii) Grail Successfully Achieved Breakthrough Device Designation from the FDA for Galleri and Received FDA Approval of an Investigational Device Exemption Application Related to Galleri

5351. {[redacted]} (Rabinowitz (Natera) Tr. 395 (*in camera*)).

5352. [redacted] (Chudova (Guardant) Tr. 1206) (*in camera*).

5353. "When a technology is needing FDA approval or a company is working with the FDA, the FDA can grant breakthrough designation which says that the technology is important key technology which can substantially impact healthcare in the United States." (Rabinowitz (Natera) Tr. 301).

5354. Breakthrough device status "will accelerate the processes of approval for that technology." (Rabinowitz (Natera) Tr. 301).

5355. [redacted] (Nolan (Freenome) Tr. 2848 (*in camera*)).

5356. An investigational device designation provides an exemption that allows a device without full FDA approval be used in certain Medicare programs. (PX7139 (Navathe Trial Dep. at 53)). Data generated through an investigational device study can be used in Medicare coverage decisions without requiring a USPSTF A or B recommendation. (PX7139 (Navathe Trial Dep. at 53)).

5357. Grail independently obtained an investigational device exemption from the FDA for Galleri. (Febbo (Illumina) Tr. 4451).

5358. [redacted] (Ofman (Grail) Tr. 3383 (*in camera*)).

5359. [redacted] (Bishop (Grail) Tr. 1466 (*in camera*); PX4489 (Grail) at 001 (Email attaching Grail BoD 2021 Budget, Dec. 2020) (*in camera*)).

5360. [redacted] (Bishop (Grail) Tr. 1469-70 (*in camera*); PX4489 (Grail) at 017 (Email attaching Grail BoD 2021 Budget, Dec. 2020) (*in camera*)).

5361. [redacted] (Bishop (Grail) Tr. 1470 (*in camera*); PX4489 (Grail) at 017 (Email attaching Grail BoD 2021 Budget, Dec. 2020) (*in camera*)).

5362. [redacted] (Bishop (Grail) Tr. 1471 (*in camera*); PX4489 (Grail) at 017 (Email from S. Green, Grail, to Grail Board of Directors, attaching Grail BoD 2021 Budget, December 9, 2020) (*in camera*)).

5363. [redacted] (Ofman (Grail) Tr. 3398 (*in camera*)).

(3) The Claimed FDA Acceleration Efficiency Is Not Verifiable Because It Is Not Quantifiable

5364. Respondents' expert, Dr. Carlton, testified that he did not independently quantify how much Illumina can accelerate the process for Galleri to achieve FDA approval. (RX6000 (Carlton Trial Dep. at 96-97); PX7134 (Carlton Dep. at 191)).

5365. Dr. Carlton relies on Illumina's deal model as a primary input into his calculation of the future quantity demanded of Galleri. (PX7134 (Carlton Dep. at 173-174)).

5366. Dr. Carlton did not attempt to independently assess the accuracy of Illumina's forecasts contained in its deal model. (PX7134 (Carlton Dep. at 174)).

5367. Dr. Carlton relies on the Hubbell paper as a critical input into his acceleration analysis and lives saved analysis. (PX7134 (Carlton Dep. at 211)).

5368. Dr. Carlton did not conduct an independent analysis of the Hubbell paper. (PX7134 (Carlton Dep. at 211)).

5369. {[redacted]} (*see* PX7134 (Carlton Dep. at 214-221) (*in camera*) {[redacted] PX7134 (Carlton Dep. at 214-221) (*in camera*)).

5370. [redacted] (PX7134 (Carlton Dep. at 221-232) (*in camera*)).

5371. [redacted]} (RX3864 (Carlton Rebuttal Report) ¶ 121, n. 294 (*in camera*)).

5372. [redacted] (PX7134 (Carlton Dep. at 227) (*in camera*)).

5373. [redacted] (PX7134 (Carlton Dep. at 227-228) (*in camera*)).

5374. [redacted]} (PX7134 (Carlton Dep. at 227-228) (*in camera*)).

5375. {[redacted]} (PX6093 (Navathe Rebuttal Report) ¶¶ 99-103 (*in camera*)).

5376. [redacted] (PX6093 (Navathe Rebuttal Report) ¶¶ 99-103 (*in camera*)).

5377. {[redacted]} (PX6093 (Navathe Rebuttal Report) ¶¶ 99-103 (*in camera*)).

5378. {[redacted]} (PX6093 (Navathe Rebuttal Report) ¶¶ 99-103 (*in camera*)).

(4) The Claimed FDA Acceleration Efficiency Is Not Merger Specific

5379. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 41) (*in camera*) (citing PX0338 at 030 n.13 (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

5380. [redacted]} (PX6092 (Rothman Rebuttal Report) ¶ 42 (*in camera*) (citing PX0338 at 029-031 (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

5381. [redacted]} (PX6092 (Rothman Rebuttal Report) ¶ 40 (*in camera*) (citing PX0338 at 030 n.13 (*Horizontal Merger Guidelines* § 10, Aug. 19, 2010)).

(a) Grail Could Enhance Its Regulatory Capabilities With Consultants or Hiring, Rather Than Merging With Illumina

5382. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 28 (*in camera*)).

5383. [redacted]} (RX6001 (Deverka Trial Dep. at 148) (*in camera*)).

5384. [redacted]} (PX6092 (Rothman Rebuttal Report) ¶ 70 (*in camera*)).

5385. [redacted]} (PX6092 (Rothman Rebuttal Report) ¶ 70 (*in camera*); *see* Freidin (Grail) Tr. 3165-66 (testifying that Grail's Chief Commercial Officer (Gautam Kollu), Grail's Senior VP of Software Engineering (Satnam Alag), and others were former employees of Illumina)).

5386. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 70 (*in camera*); Freidin (Grail) Tr. 3165-66).

5387. [redacted] (PX7111 (Fesko (Natera) Dep. at 219-220) (*in camera*)).

5388. [redacted] (Freidin (Grail) Tr. 3112 (*in camera*); PX7066 (Freidin (Grail) IHT at 275-76).

5389. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 71 (*in camera*) (citing PX7090 (Sood (Guardant) Dep. at 96-97); PX7110 (Conroy (Exact) Dep. at 27) (*in camera*)).

5390. [redacted] (PX7092 (Ofman (Grail) Dep. at 80-81) (*in camera*)).

5391. [redacted] (PX7092 (Ofman (Grail) Dep. at 82) (*in camera*)).

5392. [redacted] (PX7092 (Ofman (Grail) Dep. at 83) (*in camera*)).

5393. [redacted] (PX7092 (Ofman (Grail) Dep. at 83-84) (*in camera*)).

5394. [redacted] (PX7110 (Conroy (Exact) Dep. at 27) (*in camera*)).

5395. [redacted] (PX7110 (Conroy (Exact) Dep. at 27) (*in camera*)).

5396. [redacted] (PX7092 (Ofman (Grail) Dep. at 80-87) (*in camera*)).

5397. [redacted] (PX7092 (Ofman (Grail) Dep. at 259-260) (*in camera*)).

5398. [redacted]

[redacted] (PX6049 (Grail) at 089-90 (Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

5399. [redacted] (PX5042 (Illumina) at [redacted] (*in camera*)).

5400. Nitin Sood, Guardant's Chief Commercial Officer, testified that it was "beneficial for us [Guardant] to use outside consultants who can bring prior expertise, as Guardant itself had never gone through FDA approval prior to the approval of Guardant360." (PX7090 (Sood (Guardant) Dep. at 96-97)).

5401. [redacted] (PX7110 (Conroy (Exact) Dep. at 26-27) (*in camera*)).

(b) Companies Other Than Illumina Have Experience Relevant to Obtaining FDA PMA Approvals

5402. Illumina is not the only company to have received PMA approval from the FDA. (Ofman (Grail) Tr. 3446).

5403. Dr. Ofman testified that he did not know how many companies other than Illumina have successfully obtained PMA approval for IVD tests. (Ofman (Illumina) Tr. 3446-47).

5404. Dr. Ofman testified that there are presumably many companies, other than Illumina, with quality management systems that have met with FDA approval for IVD tests. (Ofman (Illumina) Tr. 3446) ("Q. In fact, there are many companies, other than Illumina, with quality management systems that have met with FDA approval for IVD tests. A. Presumably, yes.")).

5405. Dr. Ofman testified that Foundation Medicine and Myriad Genetics Laboratories have both successfully obtained FDA approval for NGS-based IVD tests. (Ofman (Grail) Tr. 3447-48).

5406. Foundation Medicine has obtained Class III, single-site PMAs for three different NGS-based diagnostic tests and holds more Class III PMAs for NGS-based diagnostic tests than Illumina. (Febbo (Illumina) Tr. 4447-48).

5407. Multiple other companies, including Thermo Fisher and Guardant, have also obtained PMA approval for NGS-based diagnostic tests. (*See, e.g.,* RX1659 (Illumina) at 069 (Email from Dan Poulson, Illumina, to Brian Blanchett, Illumina, June 8, 2020, attaching Decibio Liquid Biopsy Report 2019) (noting that Thermo Fisher has obtained PMA approval for an

NGS-based diagnostic test, Oncomie Dx Target); RX3299 (FDA, Guardant360 CDx – P200010, https://www.fda.gov/medical-devices/recently-approved-devices/guardant360-cdx-p200010 (last visited Feb. 10, 2022); RX3217 (FDA, PMA Database Product Listing Raw Data Full List) (listing "Approval order for Guardant360® CDx" and describing Guardant360 CDx as "a qualitative next generation sequencing-based in vitro diagnostic device")).

5408. Numerous companies, including Abbott, Becton Dickinson, Biogenex Laboratories, Bio-Merieux, Epigenomics AG, Exact Sciences, Foundation Medicine, Gen-Probe Inc., Guardant Health, Hologic, Invivoscribe, Myriad, Roche, Siemens, and Thermo Fisher, among others, have received PMA approval for IVD tests. (*See, e.g.,* RX3217 (FDA, PMA Database Product Listing Raw Data Full List) (including, among others, P190032, P190014, P200010, P160045, P970007, P160044, B160037, P040030, P120014, P130001, P130017, P020011, P080015, P160040, P190014, P140021, and P110041); RX1659 (Illumina) at 069 (Email from Dan Poulson, Illumina, to Brian Blanchett, Illumina, June 8, 2020, attaching Decibio Liquid Biopsy Report 2019)).

b) Payer Acceleration

(1) Background on Payer Reimbursement

5409. "Reimbursement" refers to payment for a medical product or service by a public or private payer. (PX7139 (Navathe Trial Dep. at 50-51)).

5410. "Coverage" refers to a payer being willing, by policy, to pay for a particular medical product or service. (PX7139 (Navathe Trial Dep. at 51)).

5411. Private or commercial insurance coverage refers to companies like Aetna, BlueCross BlueShield, and UnitedHealthcare. (Freidin (Grail) Tr. 2988).

5412. Millions of people are covered by commercial or private health insurance. (Freidin (Grail) Tr. 2987).

5413. 67.5 percent of adults ages 18 to 64 have insurance through a commercial or private payer. (Freidin (Grail) Tr. 2988).

5414. "Public payers are government entities that finance or provide directly health insurance coverage… and also maintain relationships with healthcare providers to reimburse . . . for the provision of healthcare services to covered members or beneficiaries. (PX7139 (Navathe Trial Dep. at 10-11)).

5415. Medicare is an example of a public payer. (PX7139 (Navathe Trial Dep. at 11)).

5416. Individuals 65 or over are covered by Medicare. (Freidin (Grail) Tr. 2991).

5417. Some individuals over 65 have both Medicare coverage and private insurance coverage. (*See* Freidin (Grail) Tr. 2991).

5418. Exact's CEO, Kevin Conroy, testified at trial that reimbursement of an MCED test will depend on many factors, including sensitivity and specificity of the test. (Conroy (Exact) Tr. 1735).

5419. Mr. Conroy testified at trial that reimbursement of an MCED test will also depend on whether the test is reliable, safe, effective, and medically necessary. (Conroy (Exact) Tr. 1735).

(2) The Claimed Payer Acceleration Efficiency Is Not Verifiable Because It Is Unlikely that Illumina Can Accelerate Payer Approval Compared to Grail on Its Own

(a) {[redacted]}

For evidence that Illumina and Grail's ordinary course documents did not model FDA acceleration, see Section VIII.C.1.a.2..a.

5420. Illumina's claimed reimbursement acceleration efficiency is not reflected in the base case of Illumina's deal model. (Febbo (Illumina) Tr. 4360-61).

5421. [redacted] (Febbo (Illumina) Tr. 4432 (*in camera*)).

5422. [redacted]} (PX7066 (Freidin (Grail) IHT at 281); *see* PX4096 (Grail) at 014 (Email from A. Freidin, Grail, to H. Bishop, et. al, Grail, attaching Integration Planning and Pre-Closing Activities, Oct. 23, 2020) (*in camera*)).

5423. {[redacted]} (deSouza (Illumina) Tr. 2286 (*in camera*)).

5424. {[redacted]} (deSouza (Illumina) Tr. 2286 (*in camera*)).

5425. [redacted] (Febbo (Illumina) Tr. 4432 (*in camera*)).

5426. [redacted]} (Febbo (Illumina) Tr. 4436 (*in camera*)).

5427. [redacted]} (Febbo (Illumina) Tr. 4436 (*in camera*)).

5428. [redacted] (Febbo (Illumina) Tr. 4433-34 (*in camera*)).

5429. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 18-19 (RFA No. 23) (*in camera*)).

5430. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 22-23 (RFA No. 30) (*in camera*)).

5431. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 48-49 (*in camera*)).

5432. Respondents' expert, Dr. Carlton, testified that he is "not the source" for the opinion that Illumina can accelerate the process for Galleri to achieve payer reimbursement. (RX6000 (Carlton Trial Dep. at 96-97); PX7134 (Carlton Dep. at 190-91)).

(b) Illumina and Grail Have Not Planned the Details of How Illumina Would Accelerate Coverage or Reimbursement for Galleri

For evidence that Illumina and Grail have not engaged in integration or identified specific steps for achieving FDA acceleration, see Sections VIII.C.1.a.2.b.-c.

5433. [redacted] (deSouza (Illumina) Tr. 2286-87 (*in camera*)).

5434. [redacted] (deSouza (Illumina) Tr. 2286-87 (*in camera*)).

5435. Mr. Freidin confirmed that Illumina and Grail's sales teams are not currently collaborating. (Freidin (Grail) Tr. 3157).

5436. [redacted] (deSouza (Illumina) Tr. 2288 (*in camera*)).

5437. [redacted] (Febbo (Illumina) Tr. 4434 (*in camera*)).

5438. [redacted] (PX7066 (Freidin (Grail) IHT at 278); PX4096 (Grail) at 009 (Email from A. Freidin, Grail, to H. Bishop, et. al, Grail, attaching Grail Integration Planning and Pre-Closing Activities, Oct. 23, 2020) (*in camera*)).

5439. [redacted] (Qadan (Illumina) Tr. 4245 (*in camera*)).

5440. [redacted] (Qadan (Illumina) Tr. 4232-33 (*in camera*)).

5441. [redacted] (Febbo (Illumina) Tr. 4435-36 (*in camera*)).

5442. [redacted] (Febbo (Illumina) Tr. 4435 (*in camera*)).

5443. [redacted] (Febbo (Illumina) Tr. 4435 (*in camera*)).

(c) Illumina Lacks the Resources to Effect the Alleged Payer Adoption and Market Access Efficiencies

For details on Illumina's limited relevant experience with FDA PMA approvals, see Section VIII.C.1.a.2.f.

5444. [redacted] (Qadan (Illumina) Tr. 4236 (*in camera*)).

5445. Illumina's Market Access group consists of only 13 employees. (Qadan (Illumina) Tr. 4289).

5446. [redacted] (Qadan (Illumina) Tr. 4233 (*in camera*)).

5447. {[redacted]

[redacted]}

(PX7140 (Rothman Trial Dep. at 28) (*in camera*); PX6092 (Rothman Rebuttal Report) ¶ 29 (*in camera*)).

5448. [redacted] (PX7140 (Rothman Trial Dep. at 29) (*in camera*)).

5449. [redacted]} (Qadan (Illumina) Tr. 4234 (*in camera*)).

5450. [redacted] (Qadan (Illumina) Tr. 4234 (*in camera*)).

5451. [redacted] (Qadan (Illumina) Tr. 4236-37 (*in camera*)).

5452. Illumina's Mr. Qadan estimated that Grail would need half a billion to a billion dollars to develop clinical utility data for regulatory and market access purposes. (Qadan (Illumina) Tr. 4267).

5453. Mr. Qadan testified that Illumina's Market Access group does not have the budget available for the clinical studies Galleri will require. (Qadan (Illumina) Tr. 4267-68).

5454. [redacted] (Conroy (Exact) Tr. 1691 (*in camera*)).

5455. "Illumina admits that in the U.S., Illumina's commercial sales team generally does not sell oncology products directly to primary care physicians, oncology physicians or outpatient services, and primarily focuses on selling its oncology products (such as its TSO500 therapy selection product) to pathologists in laboratories and research institutions." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 26 (RFA No. 36)).

5456. [redacted] (PX7061 (Davy

(Illumina) IHT at 217-218) (*in camera*). [redacted] (PX7061 (Davy (Illumina) IHT at 218) (*in camera*)).

5457. [redacted] (deSouza (Illumina) Tr. 2249-2250 (*in camera*); PX2549 (Illumina) at 021 (Illumina, Board of Directors Meeting, Apr. 28, 2020) (*in camera*)). [redacted] (deSouza (Illumina) Tr. 2249-2250 (*in camera*); PX2549 (Illumina) at 021 (Illumina, Board of Directors Meeting, Apr. 28, 2020) (*in camera*)).

5458. [redacted] (deSouza (Illumina) Tr. 2261-63 (*in camera);* PX5027 (Illumina) at 0011 [redacted] (*in camera*)).

5459. [redacted] (deSouza (Illumina) Tr. 2261-2263 (*in camera*); PX5027 (Illumina) at 0011 [redacted] (*in camera*)).

5460. One of Illumina's Wall Street analysts reported shortly after the announcement of the acquisition that Grail:

> represents a far stretch from [Illumina]'s core expertise, as early cancer detection through liquid biopsy requires significant market development involving lengthy large-scale clinical trials and regulatory approvals, clinical guidelines and reimbursement, as well as commercial infrastructure investment from scratch, none of which have much to leverage from [Illumina]'s core business today.

(PX2138 (Illumina) at 008 (JPMorgan, Illumina, Inc.: Searching for the (Un) Holy Grail: Deal Brings More Dilution than Test Sensitivity..., Sept. 21, 2020)).

5461. Illumina analyst Cowen Equity Research wrote:

> [W]e don't see the clear fit for acquiring a company that . . . is still at a stage where clinical studies and clinical product development are still critical and will be for years, and . . . would benefit from true clinical commercial infrastructure/reach that does not really exist at Illumina, and . . . arguably would benefit most from accessing new technologies that do not currently reside at Illumina.

(PX2138 (Illumina) at 013 (Cowen, Illumina: Reports Indicate ILMN Is Buying Grail, Sept. 21, 2020)).

5462. [redacted] } (PX6092 (Rothman Rebuttal Report) ¶ 36 (*in camera*)). { [redacted] } (PX6092 (Rothman Rebuttal Report) ¶ 36 (*in camera*)).

5463. [redacted] } (PX7140 (Rothman Trial Dep. at 24) (*in camera*)).

5464. [redacted] } (PX6092 (Rothman Rebuttal Report) ¶ 80 (*in camera*)).

5465. [redacted] } (Qadan (Illumina) Tr. 4236 (*in camera*)).

(d) The Relevance of Illumina's Payer-Related Experience Is Questionable

(i) Illumina Has No Experience Obtaining Reimbursement for a Clinical MCED Test

5466. Illumina has never received, for any product, a USPSTF recommendation. (Freidin (Grail) Tr. 3166).

5467. Illumina "admit[s] that no employee, officer, director, agent, or any individual on behalf of Illumina has met with any official of CMS or the USPSTF to discuss Medicare reimbursement coverage for GRAIL's Galleri screening test." (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 17 (RFA No. 20)).

5468. Respondents' Counsel represented at trial that "[t]he principal part of [Illumina's] business is not clinical, which is what we're focused on here, but instead research and development. . . ." (Opening Statement (Illumina) Tr. 59).

5469. [redacted] (PX7139 (Navathe Trial Dep. at 70-71 (*in camera*)). [redacted] (PX7139 (Navathe Trial Dep. at 70-71 (*in camera*)). [redacted] (PX7139 (Navathe Trial Dep. at 70-71 (*in camera*)).

(ii) Illumina's NIPT-Related Experience Is Not Directly Relevant to Accelerating Reimbursement for Galleri

For evidence on Illumina experiencing multiple delays with the FDA in the NIPT market, see Section VIII.C.1.a..2.f.ii. (Illumina's Effort to Obtain a PMA for Its NIPT Product (Project Denali) Has Experienced Multiple Delays).

5470. [redacted] (PX6093 (Navathe Rebuttal Report) ¶¶ 51-53 (*in camera*)). {[redacted] (PX6093 (Navathe Rebuttal Report) ¶ 52 (*in camera*)). {[redacted]} (PX6093 (Navathe Rebuttal Report) ¶ 52 (*in camera*)).

5471. A reason that Galleri will require different types of evidence and studies than NIPT is because NIPT has a different product profile than cancer screening. (Qadan (Illumina) Tr. 4258-59).

(iii) Illumina's Experience with Its Praxis Therapy-Selection Test Is Not Directly Relevant to Accelerating Reimbursement for Galleri

For evidence on Illumina's limited FDA experience related to its Praxis test, see Section VIII.C.1.a.2.f.i. (Illumina's Praxis Therapy Selection Test Was Approved on the Basis of a Third Party's Clinical Study).

(iv) Illumina Has Only Completed One Risk-Sharing Agreement, Which Involved NIPT

5472. Illumina has completed only one risk-sharing agreement. (Qadan (Illumina) Tr. 4249).

5473. Illumina's one completed risk-sharing agreement did not generate economic and clinical utility data for Grail's Galleri test. (Qadan (Illumina) Tr. 4252).

5474. Illumina's one completed risk-sharing agreement related to NIPT. (Qadan (Illumina) Tr. 4252).

5475. According to Ammar Qadan, Illumina's Vice President of Growth and Market Access, NIPT is not a good comparison for Galleri in terms of payor uptake. (Qadan (Illumina) Tr. 4254-55).

5476. Generating clinical and economic utility evidence for Galleri will require a different strategy than what Illumina used to generate data in NIPT. (Qadan (Illumina) Tr. 4255-56).

5477. Dr. Deverka testified during her trial deposition that Illumina has only entered into risk-sharing agreements with Harvard Pilgrim in the United States. (RX6001 (Deverka Trial Dep. at 183).

5478. Ammar Qadan, Illumina's Vice President and Global Head of Market Access, testified that [redacted]} (PX7084 (Qadan (Illumina) Dep. at 61) (*in camera*); PX6092 (Rothman Rebuttal Report) ¶ 63 (*in camera*)).

(e) Grail Already Is Independently Capable of Many of the Alleged Efficiencies from the Acquisition

5479. Dr. Deverka believes Grail can obtain reimbursement and coverage for Galleri on its own. (RX6001 Deverka Trial Dep. at 130-31).

5480. Grail recently launched Galleri as an LDT in April 2021. (RX3285 (Grail, *GRAIL Confirms Q2 2021 Introduction of Galleri*, https://grail.com/press-releases/grail-confirms-q2-2021-introduction-of-galleri-first-of-kind-multi-cancer-early-detection-blood-test) (last visited Aug. 12, 2021)).

5481. Grail's Galleri test is commercially available to patients in the United States. (Freidin (Grail) Tr. 2968-69).

5482. Galleri became commercially available nationwide in June of 2021. (Bishop (Grail) Tr. 1322).

5483. [redacted]} (RX3867 (Deverka Rebuttal Report) ¶ 112 & Table 6-1 (*in camera*)).

5484. Currently, a patient between the age of 50 and 80 can order a Galleri test from their doctor. (Freidin (Grail) Tr. 2996).

5485. Grail has a nationwide partnership with Quest Diagnostics for blood sample collection services. (Bishop (Grail) Tr. 1375-76).

5486. Galleri is "being made available under a set of regulations called laboratory-developed test." (Bishop (Grail) Tr. 1322-23).

5487. A laboratory-developed test ("LDT") is "the route to market that a very significant number of diagnostic tests are first made available to the public and doctors." (Bishop (Grail) Tr. 1323).

5488. Grail has "built all of the infrastructure, laboratory infrastructure, necessary to reliably deliver [Galleri] in full compliance with all of the regulatory requirements of running such a test in a lab." (Bishop (Grail) Tr. 1366-67).

5489. Grail's Galleri test received New York State Department of Health approval. (Ofman (Grail) Tr. 3440).

5490. Since Galleri's commercialization in June 2021 through time of trial, Grail has sold approximately 3,000 Galleri tests in the United States. (Freidin (Grail) Tr. 2969).

(i) Grail Is Pursuing Its Own Market Access Strategy

5491. [redacted] (PX7058 (Conroy (Exact) IHT at 103-04) (*in camera*)).

5492. [redacted] (*See, e.g.*, PX4209 (Grail) at 003 (Grail, Market Access Strategy, June 2020) (*in camera*) {[redacted]}; PX7058 (Conroy (Exact) IHT at 142) (*in camera*); PX7051 (Lengauer (Third Rock Ventures) IHT at 146-147) (*in camera*); PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

5493. According to Mr. Freidin, "total addressable market" is how many individuals could buy the product that is being sold. (Freidin (Grail) Tr. 2967-68).

5494. Grail estimates that in 2030 it will reach between 13 and 16 percent market penetration of the 108 million patients in its total addressable market. (Freidin (Grail) Tr. 2969).

5495. Grail is currently focused on marketing its Galleri test to large physician groups, health systems and employers. (Freidin (Grail) Tr. 2995; Della Porta (Grail) Tr. 456-57).

5496. Grail has approximately 30 to 40 people on its sales team. (Della Porta (Grail) Tr. 459).

5497. {[redacted]} (Della Porta (Grail) Tr. 525 (*in camera*)).

5498. Grail hired its sales team as part of its overall commercial plan to launch Galleri. (PX7106 (Della Porta (Grail) Dep. at 42)).

5499. [redacted]} (Ofman (Grail) Tr. 3399 (*in camera*)).

5500. To improve market penetration of Galleri, Grail plans to get FDA approval and then CMS coverage. (Freidin (Grail) Tr. 2996).

5501. [redacted] (PX0043 at 115, 132 (Grail 2020 Form S-1); PX7058 (Conroy (Exact) IHT at 87-88) (*in camera*); PX7092 (Ofman (Grail) Dep. at 175-176)).

5502. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 38 (*in camera*)).

5503. [redacted] (PX4531 (Grail) at 185 (Grail, Market Access Strategy, June 2020) (*in camera*)). {[redacted] (PX4280 (Grail) at 003-04 [redacted] (*in camera*) ({[redacted]})). Grail successfully executed contracts with multiple concierge medical practices as launch partners for Galleri. (Della Porta (Grail) Tr. 464).

5504. Grail's Form S-1 states that Grail's "market research indicates that there is a significant addressable market opportunity we can access even before approval under traditional fee-for-service Medicare reimbursement." (PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

5505. [redacted] (PX4415 (Grail) at 017-018 (Grail, Transforming Cancer Outcomes with Early Detection Testing, Feb. 24, 2021 (*in camera*)).

5506. [redacted]} (Ofman (Grail) Tr. 3372-75 (*in camera*)).

(ii) Grail Is Marketing Galleri to Health Systems

5507. Grail is targeting and selling Galleri to progressive integrated health systems. (Bishop (Grail) Tr. 1332).

5508. An integrated health system is "a health system that includes various different provisions of care ranging from primary care to hospital-delivered care and may also include payers." (Bishop (Grail) Tr. 1332).

5509. Hospitals, clinics, and physicians are associated with health systems. (Della Porta (Grail) Tr. 456-57).

5510. {[redacted]} (Ofman (Grail) Tr. 3372 (*in camera*)).

5511. Providence St. Joseph is an example of a health system. (Della Porta (Grail) Tr. 457).

5512. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 65 (*in camera*)).

5513. Providence is a "large, respected health system that includes primary care practices and hospitals." (PX7069 (Bishop (Grail) IHT at 132)).

5514. [redacted] } (Ofman (Grail) Tr. 3372-73 (*in camera*)).

5515. Mark Morgan, Grail's Senior Vice President of Market Access and Health Systems Partnerships {[redacted]} (PX7098 (Morgan (Grail) Dep. at 127) (*in camera*); *see* PX6092 (Rothman Rebuttal Report) ¶ 66, n. 104 (*in camera*)).

5516. Grail has secured a partnership with Providence. (Della Porta (Grail) Tr. 457).

5517. Providence has agreed to offer Galleri to its patients. (Della Porta (Grail) Tr. 457).

5518. [redacted] (PX4239 (Grail) at 003 (Email from M. Morgan, Grail, to C. Della Porta, Grail, Mar. 2, 2021) ("Even the suggestion that a large system will be going public soon as a GRAIL partner is generating interest…..FOMO is strong!")); *see* PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

5519. [redacted] } (Ofman (Grail) Tr. 3399 (*in camera*)).

5520. [redacted] } (PX4610 (Grail) at 002-03 (Email from J. Ofman, Grail, to S. Guttendorf, Grail, July 19, 2021) (*in camera*)). [redacted] } (PX4610 (Grail) at 002-03 (Email from J. Ofman, Grail, to S. Guttendorf, Grail, July 19, 2021) (*in camera*)).

5521. Mr. Della Porta testified at trial that Grail's health systems team is also in conversations with other potential health system partners. (Della Porta (Grail) Tr. 457).

5522. Grail's S-1 estimates the total U.S. addressable market for integrated health systems is 27 million people. (PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

(iii) Grail Is Marketing Galleri to Concierge Physicians

5523. A concierge practice is a "term used to describe primary care practices where the members of that practice or the patients pay a fee to get preferred access to highly qualified doctors." (Bishop (Grail) Tr. 1333).

5524. Concierge physicians are "physicians who in general have a membership fee for access for their patients, and . . . have a smaller numbers of patients typically." (Della Porta (Grail) Tr. 462).

5525. Grail's growth strategy team was tasked with securing initial concierge physician customers. (Della Porta (Grail) Tr. 462-63).

5526. Grail's sales team currently sells Galleri to concierge physicians. (Della Porta (Grail) Tr. 579; Bishop (Grail) Tr. 1333).

5527. Grail learned from market research that concierge physicians "tend to be early adopters of new products that their patients are interested in." (Della Porta (Grail) Tr. 462).

5528. The goal of this 2020 market research was to assess concierge physicians' interest in the Galleri test before Galleri was launched. (Della Porta (Grail) Tr. 462).

5529. Grail's 2020 market research included interviews with concierge physicians. (Della Porta (Grail) Tr. 463).

5530. Interviews between Grail and concierge physicians took place at the direction of Grail's Chief Commercial Officer, Gautam Kollu. (Della Porta (Grail) Tr. 463).

5531. Mr. Della Porta participated in some concierge physician interviews. (Della Porta (Grail) Tr. 463).

5532. [redacted] (Della Porta (Grail) Tr. 526-27 (*in camera*)).

5533. {[redacted]} (Della Porta (Grail) Tr. 527 (*in camera*)).

5534. Some concierge physicians accept insurance. (Della Porta (Grail) Tr. 462).

5535. Mr. Della Porta believes that some concierge physicians were likely to adopt Galleri. (Della Porta (Grail) Tr. 463).

5536. Grail's growth strategy team pursued deals with concierge physicians. (Della Porta (Grail) Tr. 463).

5537. Grail's growth strategy team successfully executed deals with approximately 15 concierge physicians. (Della Porta (Grail) Tr. 464).

5538. Included in these 15 concierge physicians were two of the largest concierge networks in the United States. (Della Porta (Grail) Tr. 464).

5539. The two largest concierge networks in the United States represent over 500,000 patients. (Della Porta (Grail) Tr. 464).

5540. Grail's S-1 estimates the total U.S. addressable market for concierge practices and executive health programs is 1 million people. (PX4082 (Grail) at 011 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

(iv) Grail Is Marketing Galleri to Self-Insured Employers

5541. The employer channel includes self-insured employers. (Della Porta (Grail) Tr. 457).

5542. Self-insured employers are responsible for the healthcare costs of their employees. (Della Porta (Grail) Tr. 457-58).

5543. Grail has an employer partnership team that is tasked with establishing relationships with employers. (Della Porta (Grail) Tr. 458).

5544. {[redacted]} (Ofman (Grail) Tr. 3374-75 (*in camera*)).

5545. {[redacted]} (Ofman (Grail) Tr. 3374-75 (*in camera*)).

5546. {[redacted]} (Della Porta (Grail) Tr. 525 (*in camera*)).

5547. {[redacted]} (Della Porta (Grail) Tr. 525 (*in camera*)).

5548. [redacted] (PX4610 (Grail) at 003-04 (Email from J. Ofman, Grail, to S. Guttendorf, Grail, July 19, 2021) (*in camera*)).

5549. {[redacted]} (PX4610 (Grail) at 002 (Email from J. Ofman, Grail, to S. Guttendorf, Grail, July 19, 2021) (*in camera*)).

(v) Grail Is Marketing Galleri to Life Insurance Companies

5550. Grail is in the "early stages" of securing deals with customers in the life insurance channel for Galleri. (Della Porta (Grail) Tr. 458).

5551. [redacted] (Della Porta (Grail) Tr. 529 (*in camera*)).

5552. [redacted] (Della Porta (Grail) Tr. 529 (*in camera*)).

5553. [redacted] (PX4610 (Grail) at 002 (Email from J. Ofman, Grail, to S. Guttendorf, Grail, July 19, 2021) (*in camera*)).

(vi) Grail Is Exploring Additional Innovative Channels for the Sale of Galleri

5554. Grail's new channels work involves approaching potential partners for the sale of Galleri. (Della Porta (Grail) Tr. 456).

5555. [redacted] (Della Porta (Grail) Tr. 525-26 (*in camera*)).

5556. [redacted] (Della Porta (Grail) Tr. 530 (*in camera*)).

5557. [redacted] (Della Porta (Grail) Tr. 530 (*in camera*)).

5558. Grail will publish articles in physician journals about Galleri to educate physicians about the test. (Freidin (Grail) Tr. 2995).

(vii) Grail Has Paths to Medicare Coverage for Galleri Independent of Illumina

5559. Grail's Dr. Ofman has worked on bringing technology to patients for about 25 years. (Ofman (Grail) Tr. 3449).

5560. Dr. Ofman and Grail's Head of Government Affairs, Rodger Currie, refined Grail's reimbursement strategy to accelerate opportunities for coverage through Medicare modernization. (Ofman (Grail) Tr. 3449).

5561. Grail has brought in a highly skilled group of professionals, including Mr. Currie, to help achieve Grail's reimbursement strategy. (Ofman (Grail) Tr. 3449).

5562. Grail has always made its reimbursement strategy a priority. (Ofman (Grail) Tr. 3449-50).

5563. In Dr. Ofman's judgment, Grail's reimbursement strategy has received the attention it needs. (Ofman (Grail) Tr. 3450).

5564. Under Dr. Ofman's leadership, Grail implemented a strategy to align Grail's interests with those of stakeholders who were trying to modernize Medicare. (Ofman (Grail) Tr. 3450).

5565. Grail has assembled a team in Washington, D.C. that is capable of executing on Grail's Medicare reimbursement strategy. (Ofman (Grail) Tr. 3450).

5566. [redacted] (Ofman (Grail) Tr. 3352-53 (*in camera*)).

5567. The Medicare MCED Screening Coverage Act would give CMS the authority to reimburse FDA-approved cancer screening tests including Galleri. (Bishop (Grail) Tr. 1324).

5568. If CMS identifies MCED tests as an area requiring statutory change, it could approach the congressional committees of jurisdiction to propose a statutory change to provide for coverage of MCED tests by Medicare. (PX7139 (Navathe Trial Dep. at 58-61)).

5569. [redacted] (Ofman (Grail) Tr. 3356 (*in camera*)).

5570. [redacted] (Ofman (Grail) Tr. 3356 (*in camera*)).

5571. [redacted] (Ofman (Grail) Tr. 3357 (*in camera*)).

5572. [redacted] (Ofman (Grail) Tr. 3353-54 (*in camera*)).

5573. [redacted]

} (Ofman (Grail) Tr. 3354 (*in camera*)).

5574. (Ofman (Grail) Tr. 3360 (*in camera*)).

5575. (Ofman (Grail) Tr. 3355 (*in camera*)).

5576. } (Ofman (Grail) Tr. 3355 (*in camera*)).

5577. } (Freidin (Grail) Tr. 3140; PX5044 (Grail) (LRP Review, Aug. 20, 2020) (*in camera*)).

5578. } (Freidin (Grail) Tr. 3171 (*in camera*); Bishop (Grail) Tr. 1442-43 (*in camera*); PX5044 (Grail) at 003 (LRP Review, Aug. 20, 2020) (*in camera*))).

5579. (Freidin (Grail) Tr. 3171-72 (*in camera*)).

5580. { } (Della Porta (Grail) Tr. 522 (*in camera*)). (Della Porta (Grail) Tr. 522 (*in camera*)).

5581. (Della Porta (Grail) Tr. 522 (*in camera*)).

5582. } (Della Porta (Grail) Tr. 522-24 (*in camera*)).

5583. (Conroy (Exact) Tr. 1629 (*in camera*)).

5584. (PX7139 (Navathe Trial Dep. at 53-57)).

5585. (PX7139 (Navathe Trial Dep. at 52)). {

[redacted] } (PX7139 (Navathe Trial Dep. at 52-53).

5586. { [redacted] } (PX7058 (Conroy (Exact) IHT at 26-27, 32-33) (*in camera*)).

5587. [redacted] (Conroy (Exact) Tr. 1629 (*in camera*)).

(viii) Grail Is Capable of Developing Its Own Real-World Evidence-Generating Relationships

5588. [redacted] } (PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*))).

5589. [redacted] (PX4208 (Grail) at 017 (Galleri Offering to Customers, June 2020) (*in camera*); *see* PX6092 (Rothman Rebuttal Report) ¶ 63).

5590. [redacted] } (PX6092 (Rothman Rebuttal Report) ¶ 63 (*in camera*)).

5591. Illumina has entered [redacted] } (PX4381 (Grail) at 001-002 (Email from A. Wilbekin, Grail, to M. Morgan, Grail, Apr. 12, 2021) (*in camera*)).

5592. { [redacted] } (Ofman (Grail) Tr. 3404-05 (*in camera*)).

5593. { [redacted] } (PX4381 (Grail) at 001-002 (Email from A. Wilbekin, Grail, to M. Morgan, Grail, Apr. 12, 2021) (*in camera*)).

5594. Dr. Rothman and Grail sales executive, Mark Morgan, noted that "Grail is { [redacted] } (PX6092 (Rothman Rebuttal Report) ¶ 63 (*in camera*); *see* PX7098 (Morgan (Grail) Dep. at 81) (*in camera*)).

5595. [redacted] (PX7139 (Navathe Trial Dep. at 65-66) (*in camera*)).

5596. Grail's growth strategy, market access, and sales teams all report to Grail's Chief Commercial Officer Gautam Kollu. (Della Porta (Grail) Tr. 459-60).

5597. Gautam Kollu, Grail's Chief Commercial Officer, is a former Illumina employee. (Della Porta (Grail) Tr. 454-455, 578; PX7062 (Kollu (Grail) IHT at 4, 17-18)).

5598. While at Illumina, Mr. Kollu was involved in the development of Illumina's first risk-sharing agreement as a cross-functional team member. (Qadan (Illumina) Tr. 4253-54).

5599. Dr. Deverka testified during her trial deposition that she believes Gautam Kollu, Grail's Chief Commercial Officer, has relevant experience in obtaining market access. (RX6001 (Deverka Trial Dep. at 142)).

5600. [redacted] (Ofman (Grail) Tr. 3405 (*in camera*)).

5601. [redacted] (PX7139 (Navathe Trial Dep. at 65-66); PX6093 (Navathe Rebuttal Report) ¶¶ 42, 49 (*in camera*)).

5602. [redacted] (PX7092 (Ofman (Grail) Dep. at 122-123); *see* PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

5603. [redacted] (PX4438 (Grail) at 012 [redacted] (*in camera*)).

5604. [redacted] (PX7098 (Morgan (Grail) Dep. at 127, 167-168); *see* PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

5605. [redacted] (PX4239 (Grail) at 003 (Email from M. Morgan, Grail, to C. Della Porta, Grail, Mar. 2, 2021) ([redacted]) (*in camera*); *see* PX6092 (Rothman Rebuttal Report) ¶ 66 (*in camera*)).

5606. [redacted] (PX7139 (Navathe Trial Dep. at 72-73) (*in camera*)).

5607. [redacted] (PX4213 (Grail) at 011 [redacted] (*in camera*).

5608. [redacted] (PX7139 (Navathe Trial Dep. at 67-68) (*in camera*)).

5609. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 60 (*in camera*)).

(ix) Grail Is Hitting Its Strategic Targets Toward the Commercialization of Galleri Without Illumina's Assistance

5610. [redacted] (Bishop (Grail) Tr. 1444 (*in camera*); PX5044 (Grail) at 003 (LRP Review, Aug. 20, 2020) (*in camera*)).

5611. [redacted] (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD, Grail, attaching "Investor Presentation," Aug. 20, 2020) (*in camera*)). Dr. Ofman testified that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3442).

5612. [redacted] (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD, Grail, attaching "Investor Presentation," Aug. 20, 2020) (*in camera*)). Dr. Ofman testified at trial that Grail achieved that milestone by presenting PATHFINDER results at ASCO, but said he was not sure if that occurred in the first or second half of 2021. (Ofman (Grail) Tr. 3442).

5613. The interim results for PATHFINDER were presented at ASCO in the first half of 2021. (RX3041 at 001 (Tomasz M. Beer, Interim Results of PATHFINDER, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 2021 ASCO Annual Meeting Presentation, June 4, 2021).

5614. [redacted] (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD, Grail, attaching "Investor Presentation," Aug. 20, 2020) (*in camera*)). Dr. Ofman testified at trial that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3444).

5615. [redacted] (PX4159 (Grail) at 009 (Email from J. Craighead, Grail, to Grail-BOD, Grail, attaching "Investor Presentation," Aug. 20, 2020) (*in camera*)). Dr. Ofman testified at trial that Grail achieved that milestone on schedule. (Ofman (Grail) Tr. 3444).

5616. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*)).

5617. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*)).

5618. [redacted] } (Bishop (Grail) Tr. 1466-68 (*in camera*); PX4489 (Grail) at 011 (Email from S. Green, Grail, to Grail-BOD, Grail, attaching BoD 2021 Budget, Dec. 2020) (*in camera*)).

5619. [redacted] (Freidin (Grail) Tr. 3101 (*in camera*); PX4213 (Grail) at 001 [redacted] (*in camera*)).

5620. [redacted] (Freidin (Grail) Tr. 3101-102 (*in camera*); PX4213 (Grail) at 003 [redacted] (*in camera*)).

5621. [redacted] } (PX4213 (Grail) at 003 [redacted] (*in camera*)).

5622. [redacted] (PX4213 (Grail) at 005 [redacted] (*in camera*)).

5623. [redacted] } (PX4213 (Grail) at 005 [redacted] (*in camera*)).

5624. [redacted] (PX4213 (Grail) at 005 [redacted]

[redacted] (*in camera*)).

5625. [redacted] } (Bishop (Grail) Tr. 1468 (*in camera*); PX4489 (Grail) at 011 (Email from S. Green, Grail, to Grail-BOD, Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

5626. [redacted] } (Bishop (Grail) Tr. 1468 (*in camera*); PX4489 (Grail) at 011 (Email from S. Green, Grail, to Grail-BOD, Grail, attaching BoD 2021 Budget, Dec. 9, 2020) (*in camera*)).

5627. [redacted] (PX4213 (Grail) at 00 [redacted] (*in camera*)).

5628. [redacted] } (PX4213 (Grail) at 008 [redacted] (*in camera*)).

5629. [redacted] (PX4213 (Grail) at 011 [redacted] (*in camera*)).

5630. [redacted] } (Freidin (Grail) Tr. 3102 (*in camera*)).

(x) Grail Has the Resources to Independently Commercialize Galleri at Scale

For details on Grail's access to non-merger alternatives, fundraising, and an IPO, see Section VIII.D.2.

For evidence that Grail has built an established regulatory team that has met and surpassed Grail's internal goals, see Section VIII.C.1.a.2.h. (Grail Is Already Pursuing FDA Approval Aggressively as an Independent Company).

For evidence that Grail has invested in laboratory efficiencies, including constructing a new lab in North Carolina capable of running large commercial volume covering Grail's expected volumes through 2025-2027, see Section VIII.C.5.b.).

(3) The Claimed Payer Acceleration Efficiency Is Not Verifiable Because It Is Not Quantifiable

For evidence that the claimed payer acceleration efficiency is not verifiable, see Section VIII.C.1.a.3. (The Claimed FDA Acceleration Efficiency Is Not Verifiable Because It Is Not Quantifiable).

(4) The Claimed Payer Acceleration Efficiency Is Not Merger Specific

(a) Illumina Has Provided Market Access Assistance to Other Companies

5631. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 83 (*in camera*)).

5632. [redacted] (PX7107 (deSouza (Illumina) Dep. at 248-251; *see* PX6092 (Rothman Rebuttal Report) ¶ 83, n.135 (*in camera*)).

5633. In the September 3, 2019 JPM Life Sciences CEO conference call, Mr. deSouza stated that, of the 70 companies that are doing liquid biopsy:"[w]e continue to support them in some cases, it's making sure that they have access to the best of our workflow even on the front end or on the back end." (deSouza (Illumina) Tr. 2213; PX2544 (Illumina) at 019 (Transcript of JPM Life Sciences CEO Conference Call, Sept. 3, 2019)). Mr. deSouza explained to investors that "it's planning with them what their path to a regulated offering could be, cleared offering" and that "we're continuing to work with them in a number of different ways to enhance their ability to expand their market, because, what's good for them is obviously good for us too." (deSouza (Illumina) Tr. 2213; PX2544 (Illumina) at 019 (Transcript of JPM Life Sciences CEO Conference Call, Sept. 3, 2019)).

(b) Illumina Provided Advantages to Grail While Grail Was a Separate Corporate Entity

For additional information on how Illumina gave Grail preferential, exclusive, and customized treatment when it owned more than 50 percent of Grail (but not once it spunoff Grail), see Sections I.A.2.–3. (Formation of Grail & Spinoff of Grail (Reducing Ownership to Less Than 50 Percent) and VII.D.1. (Illumina Identified Tools When it Launched and Spun Off Grail).

5634. As noted in Illumina's board minutes, when Illumina owned a majority stake in Grail before selling it to outside investors, 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)).

5635. In a December 2015 board presentation prior to Grail's spinoff, Illumina planned to provide Grail with "[s]pecial [p]ricing," a 75 percent discount that would save Grail $100 million over three years. (PX2069 (Illumina) at 003 (Python Board Approval, Dec. 20, 2015)).

(c) Illumina Has Incentives to Accelerate Commercialization of Galleri Without the Merger

For evidence relevant to Illumina's incentives to accelerate Galleri without a merger, see Section VIII.C.1.g. (If Illumina Could Meaningfully Accelerate Galleri, It Has the Incentive to Do So Absent the Merger).

(d) Grail Could Finance Commercialization of Galleri at Scale Through an IPO or Other Fundraising

For evidence that Grail had non-merger alternatives to commercializing Galleri, see Section VIII.D. (Non-Merger Alternatives Could Replicate Illumina's Claimed Efficiencies).

(e) Experience Forming Payer Relationships Can Be Accessed Outside of Illumina

5636. Other companies than Illumina are able to enter into relationships with payers. (Freidin (Grail) Tr. 3164).

5637. Illumina did not invent risk-sharing agreements. (Qadan (Illumina) Tr. 4249).

5638. [redacted] (PX7139 (Navathe Trial Dep. at 62-63) (*in camera*); PX6093 (Navathe Rebuttal Report) ¶¶ 39-40 (*in camera*)).

5639. [redacted] (PX7139 (Navathe Trial Dep. at 63-64; PX6093 (Navathe Rebuttal Report) ¶ 40 (*in camera*)).

5640. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 40 (*in camera*)).

5641. Harvard Pilgrim gained experience in risk-based contracts after completing its risk-based agreement with Illumina. (Qadan (Illumina) Tr. 4272).

5642. [redacted]

[redacted]} (PX6093 (Navathe Rebuttal Report) ¶¶ 43-46 (*in camera*)).

5643. [redacted]} (PX6091 (Scott Morton Rebuttal Report) ¶ 78 (*in camera*)).

(f) Clinical Research Organizations and Consultants Can Help to Develop Evidence of Clinical Utility

5644. Mr. Qadan testified that companies can recruit clinical research organizations to run the operational aspects of a clinical utility study. (Qadan (Illumina) Tr. 4268).

5645. [redacted]} (PX7139 (Navathe Trial Dep. at 77) (*in camera*)).

(g) Consultants Are Available in Connection with Market Access and to Assist in Obtaining Payer Reimbursement

In addition to the below, see Section VIII.C.1.a.4.a. (Grail Could Enhance Its Regulatory Capabilities With Consultants or Hiring, Rather Than Merging With Illumina).

5646. Companies can hire consultants to understand how commercial payers would look at a particular test. (Qadan (Illumina) Tr. 4268).

5647. Mr. Morgan testified that Grail has consulted with ClearView regarding pricing. (PX7098 (Morgan (Grail) Dep. at 64-65)).

5648. In a presentation prepared for [redacted] (PX4138 (Grail) at 124 (Email from M. Morgan, Grail, to N. Aceto, Grail, copying G. Kollu and J. Ofman, Grail, June 22, 2020) (*in camera*); PX6092 (Rothman Rebuttal Report) ¶ 63 (*in camera*)).

5649. Mr. Morgan testified that Grail consulted with ADVI regarding Medicare adoption. (PX7098 (Morgan (Grail) Dep. at 65). ADVI provided Grail with "insights and inputs that help [Grail] shape [its] strategy on the government side." (PX7098 (Morgan (Grail) Dep. at 64)).

5650. Mr. Morgan testified that ADVI provided Grail with insights into how to "put the best submission forward to a Medicare administrative contractor as possible" and "the type of evidence, clinical evidence," that Medicare may value. (PX7098 (Morgan (Grail) Dep. at 65)).

5651. Mr. Morgan testified that Grail consulted with McDermott regarding the "complexity associated with coding to help . . . GRAIL understand how to navigate that [Medicare] landscape." (PX7098 (Morgan (Grail) Dep. at 68-69).

5652. Mr. Morgan testified that [redacted] (PX7098 (Morgan (Grail) Dep. at 131-132) (*in camera*)).

5653. [redacted] (PX7092 (Ofman (Grail) Dep. at 80-87) (*in camera*)).

5654. Ammar Qadan, Illumina's Vice President and Global Head of Market Access, testified that Illumina has [redacted] (PX7084 (Qadan (Illumina) Dep. at 27-29) (*in camera*)).

5655. Mr. Qadan testified that [redacted] (PX7084 (Qadan (Illumina) Dep. at 27-29) (*in camera*)).

5656. Mr. Qadan testified that [redacted] (PX7084 (Qadan (Illumina) Dep. at 27-29) (*in camera*)).

5657. Illumina hired Dr. Lee Newcomer as a consultant to understand how commercial payers would look at the Galleri test. (Qadan (Illumina) Tr. 4268).

5658. [redacted] (PX7084 (Qadan (Illumina) Dep. at 118-119) (*in camera*)).

5659. Illumina's market access group uses Ipsos, a consulting firm, to develop its monthly dashboard regarding global coverage and reimbursement for Illumina's products. (Qadan (Illumina) Tr. 4275).

5660. Illumina's market access group hired Bruce Quinn Associates as a consultant. (Qadan (Illumina) Tr. 4275).

5661. Illumina has used Deloitte as a consultant to build strategy for rare, undiagnosed genetic diseases. (Qadan (Illumina) Tr. 4275).

5662. Illumina has consulted Deloitte regarding "innovative contracting mechanisms." (Qadan (Illumina) Tr. 4275-76).

5663. An Illumina employee involved in developing Illumina's NIPT risk-sharing agreement with Harvard Pilgrim, Rick Nida, left Illumina and is now a principal and senior vice president at GenoSan Genomic and Diagnostic Commercialization Consulting. (Qadan (Illumina) Tr. 4254).

5664. [redacted] (PX7139 (Navathe Trial Dep. at 76-77) (*in camera*)).

5665. [redacted] (PX7139 (Navathe Trial Dep. at 77) (*in camera*)).

(h) Grail Can Hire Employees to Build Relationships and Fill Any Gaps in Its Experience

In addition to the below, for more evidence on Grail's plans and ability to hire relevant experience, see Section VIII.C.1.a.4.a. (Grail Could Enhance Its Regulatory Capabilities With Consultants or Hiring, Rather Than Merging With Illumina).

5666. {[redacted]} (PX7083 (Bishop (Grail) Dep. at 155) (*in camera*)).

5667. Grail previously has hired multiple employees from Illumina, including executive-level employees involved in market access, sales, software, and other project areas, such as Gautam Kollu (Grail Chief Commercial Officer), Linda Mansolillo (Grail Senior Director, National Accounts), and Satnam Alag (Grail Senior VP of Software Engineering and Chief Security Officer). (Freidin (Grail) Tr. 3165-66).

5668. [redacted] (PX6093 (Navathe Rebuttal Report) ¶ 63 (*in camera*); PX7116 (Dolan (Quest) IHT at 1170-72)). Once employed by Grail, Ms. Mansolillo continued to work with Quest to conclude a phlebotomy collaboration for Galleri. (PX7116 (Dolan (Quest) IHT at 169-174)). {[redacted]} (PX4585 (Grail) at 002-003 (Email from L. Mansolillo, Grail, to M. Westlund, Providence, July 31, 2020) (*in camera*); PX6093 (Navathe Rebuttal Report) ¶ 63 (*in camera*)).

5669. [redacted] (RX6001 (Deverka Trial Dep. at 148) (discussing RX3867 (Deverka Rebuttal Report) ¶¶ 112-13 (*in camera*)).

(i) Illumina's Alleged Technology and Process Benefits to Grail Are Not Unique to Illumina

5670. [redacted]} (RX2762 (Grail) at 033 (Email from M. Ramirez, Grail, to B. Chang, Grail, attaching "Science, Medicine & Technology Committee Meeting Materials," May 26, 2021) (*in camera*)).

5671. [redacted]

[redacted]} (Ofman (Grail) Tr. 3389 (*in camera*); RX2762 (Grail) at 033 (Email from M. Ramirez, Grail, to B. Chang, Grail, attaching "Science, Medicine & Technology Committee Meeting Materials," May 26, 2021) (*in camera*)).

5672. [redacted]} (PX6092 (Rothman Rebuttal Report) ¶¶ 73-84 (*in camera*)).

(i) Exact/Thrive

5673. Exact was able to build capacity from a very small lab to now the ability to offer millions of Cologuard tests and hundreds of thousands of Oncotype DX tests and other tests, and constantly invests in those clinical laboratory capabilities. (Conroy (Exact) Tr. 1534-35).

5674. Exact recruited its sales force from "[a]ll over the country from people primarily who had experience calling on healthcare providers and in particular primary care healthcare providers." (Conroy (Exact) Tr. 1536).

For evidence on how Exact built its salesforce as a start-up firm and formed a sales partnership with Pfizer, see Section VI.A.8.c. (Exact Built its Salesforce from Scratch, Expanding as Cologuard Received Regulatory Approvals and Reimbursement Status) and

2. Elimination of Double Marginalization

5675. Dr. Scott Morton explained that {[redacted]} (PX6090 (Scott Morton Report) ¶ 279 (*in camera*)).

5676. Dr. Scott Morton explained that [redacted] (PX6090 (Scott Morton Report) ¶ 279 (*in camera*)).

5677. [redacted] (PX6090 (Scott Morton Report) ¶¶ 284-286 (*in camera*)).

a) EDM Is Not Merger Specific

5678. [redacted] (PX7138 (Scott Morton Trial Dep. at 68-69); PX6090 (Scott Morton Report) ¶ 280 (*in camera*)).

5679. [redacted] (PX6090 (Scott Morton Report) ¶ 280 (*in camera*)).

5680. [redacted] (PX7138 (Scott Morton Trial Dep. at 68-69) (*in camera*); PX6090 (Scott Morton Report) ¶ 280 (*in camera*)).

5681. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 39 (*in camera*)). Thus, [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 39 (*in camera*)).

5682. [redacted] PX6090 (Scott Morton Report) ¶ 280 (*in camera*)). [redacted] (PX6090 (Scott Morton Report) ¶ 281 (*in camera*)).

5683. [redacted] (PX6090 (Scott Morton Report) ¶¶ 181-182 (*in camera*)).

5684. [redacted] (PX6090 (Scott Morton Report) ¶ 181 (*in camera*)).

5685. Dr. Carlton testified that the premerger relationship between Illumina and Grail had some non-linear pricing elements, including volume-based discounts, royalties, and Illumina's partial ownership interest in Grail. ((RX6000 (Carlton Trial Dep. at 144-145)).

5686. [redacted] (PX7123 (Fellis (Illumina) Dep. at 27-30, 35) (*in camera*)).

5687. [redacted] (PX7076 (Berry (Illumina) Dep. at 115-119) (*in camera*); *see* PX7123 (Fellis (Illumina) Dep. at 53-54) (*in camera*)).

5688. [redacted] (PX7076 (Berry (Illumina) Dep. at 176-77) (*in camera*).

5689. [redacted] (PX7076 (Berry (Illumina) Dep. at 177) (*in camera*)).

5690. Ms. Berry testified that "different pricing sensitivity potentially could exist across different customer segments," and Illumina uses that in determining how to price its products. (PX7076 (Berry (Illumina) Dep. at 174); PX2387 (Illumina) at 001 (Email from N. Berry, Illumina, to T. Lialin, Illumina, Apr. 19, 2018) ([redacted]) (*in camera*)).

5691. [redacted] (PX2391 (Illumina) at 001 (Email from N. Berry, Illumina, to P. Dueppen, Illumina, Jan. 29, 2021) (*in camera*)).

5692. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 37 (*in camera*)).

5693. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 39 (*in camera*)).

5694. [redacted] (PX6090 (Scott Morton Report) ¶ 284 (*in camera*) (emphasis in original)).

5695. [redacted] (PX7138 (Scott Morton Trial Dep. at 68-69) (*in camera*); *see also* PX6090 (Scott Morton Report) ¶ 287 (*in camera*)).

5696. [redacted] (PX6090 (Scott Morton Report) ¶ 287 (*in camera*)).

5697. [redacted] (PX7138 (Scott Morton Trial Dep. at 71) *see also* (PX6090 (Scott Morton Report) ¶ 287 (*in camera*)).

5698. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 46 (*in camera*))).

5699. [redacted] (PX7138 (Scott Morton Trial Dep. at 70-71) (*in camera*); PX6090 (Scott Morton Report) ¶¶ 285-286 (*in camera*)).

5700. [redacted] (PX6090 (Scott Morton Report) ¶ 285 (*in camera*)).

5701. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 37 (*in camera*)).

5702. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 39 (*in camera*)).

5703. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 37 (*in camera*)).

5704. [redacted] (PX6090 (Scott Morton Report) ¶ 286 (*in camera*)).

5705. [redacted] (PX6090 (Scott Morton Report) ¶ 293 (*in camera*)).

b) EDM Is Not Verifiable (And, if Applicable, Not Quantified)

5706. Dr. Carlton testified that he did not "estimate[] a model or estimate the passthrough" to determine the net effect of EDM that will result from the Acquisition. ((PX7134 (Carlton Dep. at 122-123)).

5707. [redacted] ((RX6000 (Carlton Trial Dep. at 65-66) (*in camera*)).

5708. [redacted] (RX6000 (Carlton Trial Dep. at 65-66) (*in camera*)).

5709. Dr. Carlton testified that, in order to properly quantify the value of EDM due to the Acquisition, he would need to rely on a full vertical model, including the amount of diversion, elasticity of demand, and the opportunity cost of not serving Grail's rivals. ((RX6000 (Carlton Trial Dep. at 134-135); PX7134 (Carlton Dep. at 123-124)).

5710. Dr. Carlton testified that he did not create a full vertical model to calculate the value of EDM resulting from the Acquisition. (RX6000 (Carlton Trial Dep. at 136-137)).

5711. Dr. Carlton testified that "I don't think you can assume necessarily any particular pass-through rate, and it's a mistake to think that you can solely calculate EDM without considering a model where you consider" factors such as price, marginal costs, and diversion ratio. (PX7134 (Carlton Dep. at 123-127)). [redacted] (PX7134 (Carlton Dep. at 126-127) (*in camera*)).

5712. [redacted] (RX3864 (Carlton Rebuttal Report) ¶¶ 11, 101 n.256, 104 n.258 (*in camera*)).

5713. [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 101 n.256 (*in camera*)).

5714. [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 104 n.258 (*in camera*)).

5715. [redacted]

[redacted] (RX3864 (Carlton Rebuttal Report) ¶ 104 (*in camera*)).

c) Respondents Fail to Demonstrate That Any Claimed Cost Savings from EDM Will Be Passed Through to Customers

5716. Dr. Carlton testified that he did not create a model to estimate the percentage of EDM that will be passed through to consumers as a result of the Acquisition. (PX7134 (Carlton Dep. at 122-123)).

5717. Dr. Carlton testified that he did not estimate the percentage of EDM that will be passed through to consumers as a result of the Acquisition. (PX7134 (Carlton Dep. at 122-123)).

5718. Dr. Carlton testified that the pass through rate cannot be estimated without a fully specified model. (PX7134 (Carlton Dep. at 123-24)).

5719. Dr. Carlton testified that the pass through rate cannot be estimated independent of the raising rivals' costs effect. (PX7134 (Carlton Dep. at 123-44)).

5720. Dr. Carlton conceded that, in this case, he cannot necessarily assume any particular pass through rate. (PX7134 (Carlton Dep. at 126-7)).

3. R&D Efficiencies

a) The Claimed R&D Efficiency Is Not Verifiable

5721. Dr. Rothman concluded that [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 86 (*in camera*)).

5722. Dr. Rothman explained that [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 89, n. 146 (*in camera*)). [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 89, n. 146 (*in camera*)).

5723. [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 33 (*in camera*)).

5724. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 33 (*in camera*)).

5725. Dr. Rothman noted that [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 87 (*in camera*)).

5726. Dr. Rothman explained that {[redacted]} (PX6092 (Rothman Rebuttal Report) ¶ 88 (*in camera*)).

5727. Dr. Carlton testified that he did not quantify the benefit of R&D efficiency in his report. (RX6000 (Carlton Trial Dep. at 120)).

5728. Dr. Carlton testified that he has not attempted to estimate the scale of R&D efficiencies. (RX6000 (Carlton Trial Dep. at 120)).

5729. With regard to R&D efficiencies, Dr. Carlton testified, "I think it's hard to make predictions as to exactly what R&D efficiencies would result." (RX6000 (Carlton Trial Dep. at 120)).

5730. Dr. Carlton testified that he did not perform an independent calculation of costs associated with Illumina and Grail directing their efforts toward any R&D efficiencies. (RX6000 (Carlton Trial Dep. at 120-121)).

5731. Dr. Carlton did not attempt to assign a specific probability to the likelihood that new health products will be identified through the claimed R&D efficiencies. (RX6000 (Carlton Trial Dep. at 121)).

5732. Dr. Carlton testified that he did not independently attempt to identify what specific products may result from the claimed R&D efficiencies. (RX6000 (Carlton Trial Dep. at 121-122)).

5733. Mr. deSouza testified that Illumina has not developed a commercial plan for any test that might result from the claimed R&D efficiency. (deSouza (Illumina) Tr. 2425).

5734. Mr. deSouza testified that Illumina has not formed the research teams to develop screening products for fatty liver disease and Parkinson's. (deSouza (Illumina) Tr. 2423).

5735. Dr. Aravanis, Illumina's corporate representative, testified that as of Illumina's March 30, 2021, Rule 2.7(h) investigational hearing, "Illumina [had] not attempted to quantify these [claimed R&D efficiencies]." (PX7073 at 60 (Aravanis 2.7(h) IHT)).

5736. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 33 (*in camera*)**;** ***see*** PX7107 (deSouza (Illumina) Dep. at 146, 164)). [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 33, 88 (*in camera*)).

5737. [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 33, 88 (*in camera*) (citing PX0064 at 009 (Illumina Open Offer Agreement, Mar. 29, 2021)**).** [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 33, 88 (*in camera*)). [redacted] (PX6092 (Rothman Rebuttal Report) ¶¶ 33, 88 (*in camera*)).

5738. [redacted] (Jamshidi (Grail) Tr. 4067 (*in camera*)).

5739. [redacted] (Jamshidi (Grail) Tr. 4067-68 (*in camera*)).

5740. [redacted] (Jamshidi (Grail) Tr. 4067-68 (*in camera*)).

5741. [redacted] (Jamshidi (Grail) Tr. 4067 (*in camera*)).

5742. [redacted] (PX4489 (Grail) at 066 (Grail BoD 2021 Budget, Dec. 2020) (*in camera*)).

5743. [redacted] (Jamshidi (Grail) Tr. 4067 (*in camera*)).

5744. [redacted] (RX3867 (Deverka Rebuttal Report) at Table 6-1 (*in camera*)).

5745. [redacted] (Jamshidi (Grail) Tr. 4061 (*in camera*)).

5746. [redacted] (Jamshidi (Grail) Tr. 4061 (*in camera*)).

5747. [redacted] (Jamshidi (Grail) Tr. 4055 (*in camera*)).

5748. [redacted] (Jamshidi (Grail) Tr. 4056 (*in camera*)).

5749. [redacted] (Jamshidi (Grail) Tr. 4057 (*in camera*)).

5750. [redacted] (Jamshidi (Grail) Tr. 4058 (*in camera*)).

5751. [redacted] (Jamshidi (Grail) Tr. 4058 (*in camera*)).

b) The Claimed R&D Efficiency Is Not Merger Specific

5752. Dr. Aravanis testified that "GRAIL has some preliminary findings that the methylation technology can be useful for detecting fatty liver disease and, in particular, a very advanced form of that disease." (Aravanis (Illumina) Tr. 1954-1955).

5753. Dr. Aravanis testified that, beyond fatty liver disease, "there's evidence of other types of diseases that can be detected using Grail's methylation technology. These include metabolic diseases, cardiovascular disease, you know, heart attacks, psychiatric diseases." (Aravanis (Illumina) Tr. 1955).

5754. Dr. Rothman explained that [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 91 (*in camera*)). [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 91 (*in camera*)).

5755. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 111 (*in camera*)).

5756. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 111 (*in camera*)).

4. Elimination of Grail Royalty

a) Elimination of the Royalty Is Not Merger Specific

5757. Grail entered into a supply agreement with Illumina in 2017. (Freidin (Grail) Tr. 2975).

5758. The Grail-Illumina supply agreement was entered into during Grail's Series B fund raise and deconsolidation from Illumina. (Freidin (Grail) Tr. 2975).

5759. According to Mr. Freidin, Grail agreed to pay a royalty on all the products that Grail creates in the cancer space in perpetuity. (Freidin (Grail) Tr. 2975-76).

5760. [redacted] (Freidin (Grail) Tr. 3029 (*in camera*)).

5761. GRAIL conducted analysis of the effect a royalty would have on Grail's ability to price and sell the Galleri product. (Freidin (Grail) Tr. 2976-77).

5762. Before Illumina offered to buy Grail, Grail evaluated ways to eliminate the Illumina royalty. (Freidin (Grail) Tr. 2978).

5763. Grail engaged with its advisor, Morgan Stanley, to run scenarios that could defer, eliminate, or decrease the Illumina royalty. (Freidin (Grail) Tr. 2978).

5764. [redacted] (Freidin (Grail) Tr. 3030 (*in camera*)).

5765. [redacted] . (Freidin (Grail) Tr. 3083 (*in camera*)).

5766. [redacted] (Freidin (Grail) Tr. 3083 (*in camera*)).

5767. [redacted] (Freidin (Grail) Tr. 3084 (*in camera*)).

5768. {[redacted]} (Freidin (Grail) Tr. 3084-85 (*in camera*)).

5769. [redacted] (Freidin (Grail) Tr. 3085 (*in camera*)).

5770. [redacted] (Freidin (Grail) Tr. 3085 (*in camera*); PX4235 (Grail) at 018 (Email from M. Podoll, Morgan Stanley, to A. Tosti, Grail, CC'ing A. Freidin, Grail, May 3, 2020 (*in camera*)).

5771. [redacted] (Freidin (Grail) Tr. 3086 (*in camera*); PX4235 (Grail) at 018 (Email from M. Podoll, Morgan Stanley, to A. Tosti, Grail, CC'ing A. Freidin, Grail, May 3, 2020 (*in camera*)).

5772. [redacted] (Freidin (Grail) Tr. 3086 (*in camera*)).

5773. [redacted] (RX6000 (Carlton Trial Dep. at 126) (*in camera*)).

5774. {[redacted]} (PX7066 (Freidin (Grail) IHT at 192-193; PX4235 (Grail) at 004 (Email from M. Podoll, Morgan Stanley, to A. Tosti, Grail, CC'ing A. Freidin, Grail, May 3, 2020 (*in camera*)).

5775. {[redacted]} (Freidin (Grail) Tr. 3086-87 (*in camera*); PX7066 (Freidin (Grail) IHT at 192-193)).

5776. [redacted] (PX6091 (Scott Morton Rebuttal Report) ¶ 44 (*in camera*)).

5777. Dr. Carlton testified that he did not specifically opine on whether the royalty that Grail paid to Illumina could not have been eliminated absent the merger. (RX6000 (Carlton Trial Dep. at 125)).

b) Elimination of the Royalty Is Not Verifiable

5778. [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 110 (*in camera*)). {[redacted]

[redacted] (RX3864 (Carlton Rebuttal Report) ¶ 110 n.270 (*in camera*)).

5779. Dr. Carlton explained that [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 110 n.270 (*in camera*)).

c) Respondents Fail To Demonstrate That Elimination of the Royalty Will Be Passed Through to Customers

5780. [redacted] (*see* RX3864 (Carlton Rebuttal Report) (*in camera*)).

5781. To the extent that a reduction in royalty payments from Grail to Illumina reduces the margin charged by the combined firm post-Acquisition, such a reduction in margin will be offset by the issuance of CVRs. (PX0408 at 018 (Illumina Form 10-Q for Q3 2021)).

5782. [redacted] (Freidin (Grail) Tr. 3078 (*in camera*); PX4047 (Grail) at 045 (Email From M. Song, Grail, to Hans Bishop, Grail, et al., attaching Discussion Materials: Project Valor, Sept. 16, 2020)).

5783. Illumina valued the CVR consideration owed to Grail's stockholders at $762 million as of the acquisition's August 18, 2021 completion date. (PX0408 at 018 (Illumina Form 10-Q for Q3 2021)). Illumina measured this CVR value using several assumptions that included "forecasted revenues for GRAIL." (PX0408 at 018 (Illumina Form 10-Q for Q3 2021)).

5784. On August 18, 2021, Illumina announced "Holders of approximately 47% of GRAIL equity interests and/or awards (on a fully diluted basis), or 54% excluding Illumina, elected to receive the CVR consideration." (PX0377 at 002 (Press Release: Illumina Acquires GRAIL to Accelerate Patient Access to Life-Saving Multi-Cancer Early-Detection Test, dated Aug. 18, 2021)).

5785. Dr. Carlton testified that he did not analyze the tax treatment of CVRs given to Grail shareholders compared to the tax treatment of royalties that Grail paid to Illumina. (RX6000 (Carlton Trial Dep. at 127)).

5. Lab and Supply Chain Cost Savings

a) The Claimed Lab and Supply Chain Cost Savings Efficiency Is Not Verifiable (And, if Applicable, Not Quantified)

5786. Respondents did not include efficiencies related to supply chain and laboratory operations in their Answer. (*See generally* Respondents' Answer).

5787. [redacted] (PX6069 (Illumina Responses & Objections to FTC Requests for Admissions) at 20 (RFA No. 26) (*in camera*)).

5788. During the March 30, 2021, Illumina Rule 2.7(h) investigational hearing, Dr. Aravanis testified that Illumina's quantification of the claimed supply chain and laboratory operation efficiencies was prepared in the week prior to his testimony. (PX7073 (Aravanis (Illumina) IHT at 45-46); *see* PX6050 (Illumina) at 003-005 (Aravanis Investigational Hearing Notes)).

5789. [redacted] (Ofman (Grail) Tr. 3382 (*in camera*)).

5790. [redacted] (Ofman (Grail) Tr. 3381 (*in camera*)).

5791. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 92 (*in camera*)).

5792. [redacted] (PX6092 (Rothman Rebuttal Report) ¶ 93 (*in camera*)).

5793. [redacted] (RX3864 (Carlton Rebuttal Report) ¶ 104 n. 262 (*in camera*) (citing PX2613 (Illumina) at 002 (Appendix A: Illumina/GRAIL Efficiency Analysis)).

5794. [redacted] (PX2613 (Illumina) at 004 (Appendix A: Illumina/Grail Efficiency Analysis)).

5795. [redacted] (PX2613 (Illumina) at 005 (Appendix A: Illumina/Grail Efficiency Analysis)).

5796. Dr. Carlton testified that he is not the source of the claim that Illumina will achieve supply chain and operational efficiencies. (RX6000 (Carlton Trial Dep. at 127)).

5797. Dr. Carlton testified that he did not perform an independent quantification of variable cost savings from supply chain and operational efficiencies. (RX6000 (Carlton Trial Dep. at 128)).

5798. Dr. Carlton testified that he did not account for any costs associated with Illumina and Grail working to achieve supply chain and operational efficiencies. (RX6000 (Carlton Trial Dep. at 128-129)).

5799. Dr. Carlton testified that he did not independently attempt to quantify any costs associated with Illumina and Grail working to achieve supply chain and operational efficiencies. (RX6000 (Carlton Trial Dep. at 129)).

b) The Claimed Lab and Supply Chain Cost Savings Efficiency Is Not Merger Specific

5800. Dr. Carlton did not perform an analysis to determine whether the supply chain and operational efficiencies claimed by Illumina are merger specific. (RX6000 (Carlton Trial Dep. at 128)).

5801. [redacted] (*See* PX4016 (Grail) at 025 (Grail Strategy Planning Roadmap (Workshop #2), Sept. 2, 2020) (*in camera*) [redacted]; *see also* PX4491 (Grail) at 007, 035-043 (Board of Directors Meeting, Apr. 30, 2019) (*in camera*)).

5802. Grail has been running commercial tests in its Menlo Park lab. (Freidin (Grail) Tr. 3005).

5803. [redacted] (Freidin (Grail) Tr. 3104 (*in camera*)).

5804. [redacted] (Ofman (Grail) Tr. 3386 (*in camera*)).

5805. [redacted] (Freidin (Grail) Tr. 3002; *see* PX4175 (Grail) at 099-108 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5806. [redacted] (Bishop (Grail) Tr. 1469-70 (*in camera*); PX4489 (Grail) at 017 (Email from S. Green, Grail, to grail-bod, attaching BoD 2021 Budget, Dec. 2020) (*in camera*)).

5807. Grail is pursuing a centralized approach at the RTP lab because it is "the fastest way" for Grail to process millions of tests. (Freidin (Grail) Tr. 3006-007).

5808. Grail is building a second laboratory "to invest in additional test capacity to meet anticipated future demand" and because it is "investing very heavily in new technology, including robotics, to reduce the cost of the test and [] speed up the turnaround time of the test." (Bishop (Grail) Tr. 1377-78).

5809. [redacted] (Bishop (Grail) Tr. 1462 (*in camera*); *see* PX5045 (Grail) at 098-99 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5810. [redacted] (PX6082 (Grail Responses & Objections to FTC Requests for Admissions) at 8 (RFA No. 6) (*in camera*)).

5811. Building a second lab will provide Grail with "uninterrupted ability to run clinical trials" and "create new capacity at [Grail's California] lab to support clinical trials." (Bishop (Grail) Tr. 1378).

5812. [redacted] (Freidin (Grail) Tr. 3104 (*in camera*)).

5813. [redacted] (Freidin (Grail) Tr. 3104 (*in camera*)).

5814. [redacted] (Freidin (Grail) Tr. 3104 (*in camera*)).

5815. [redacted] (PX7066 (Freidin (Grail) IHT at 44-45); PX4175 (Grail) at 099 (Grail Board Session Meeting Materials, Sept. 10, 2020 (*in camera*)).

5816. [redacted] (Bishop (Grail) Tr. 1464 (*in camera*); PX5045 (Grail) at 106 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5817. Mr. Bishop testified that the building for the second laboratory has been constructed. (Bishop (Grail) Tr. 1427).

5818. Grail received a certificate of occupancy for the second laboratory. (Bishop (Grail) Tr. 1427).

5819. Grail has hired employees to work in the second laboratory. (Bishop (Grail) Tr. 1427).

5820. Grail has already purchased equipment for the RTP lab. (Bishop (Grail) Tr. 1427-28).

5821. [redacted] (Freidin (Grail) Tr. 3103 (*in camera*)).

5822. Grail expects to validate the new lab for the purpose of supplying Galleri towards the end of 2021. (Bishop (Grail) Tr. 1378-79).

5823. Grail plans to continue building out the new lab "for additional capacity" and gaining "regulatory approvals." (Bishop (Grail) Tr. 1379).

5824. [redacted] (Bishop (Grail) Tr. 1446-47 (*in camera*); PX5044 (Grail) at 016 (LRP Review, Aug. 20, 2020)).

5825. Grail already incorporates automation into its processes for Galleri. (PX7066 (Freidin (Grail) IHT at 227-28)).

5826. [redacted] (Ofman (Grail) Tr. 3387 (*in camera*)).

5827. [redacted] (PX6082 (Grail Responses & Objections to FTC Requests for Admissions) at 9-10 (RFA No. 10) (*in camera*)).

5828. [redacted] (Freidin (Grail) Tr. 3042 (*in camera*)).

5829. [redacted] (Freidin (Grail) Tr. 3042 (*in camera*)).

5830. [redacted] (Bishop (Grail) Tr. 1447 (*in camera*)).

5831. [redacted] (Freidin (Grail) Tr. 3042-43 (*in camera*)).

5832. [redacted] (Freidin (Grail) Tr. 3043 (*in camera*)).

5833. [redacted] (Freidin (Grail) Tr. 3042-43 (*in camera*)).

5834. Grail has a dedicated supply chain team to examine supply chain risk and a supplier review board. (PX7066 (Freidin (Grail) IHT at 146-47)).

5835. [redacted] (PX7061 (Davy (Illumina) IHT at 232–233) (*in camera*); PX7063 (Berry (Illumina) IHT at 78)).

5836. [redacted]

[redacted]} (PX7064 (Goswami (Illumina) IHT at 260) (*in camara*) (discussing PX2163 (Illumina) at 011[redacted]; *see* PX7087 (Goswami (Illumina) Dep. at 166-167) ({[redacted]}) (*in camera*)).

6. Other Claimed Efficiencies Are Neither Verifiable nor Merger Specific

a) Acceleration of International Testing and Expansion of Galleri Is Not Verifiable or Merger Specific

5837. At the time of Mr. Qadan's May 26, 2021, deposition, Illumina had not discussed acceleration of Galleri with payers outside the United States. (Qadan (Illumina) Tr. 4277; PX7084 (Qadan (Illumina) Dep. at 176-77)).

5838. Illumina did not analyze how payer adoption outside the United States would impact coverage in the United States. (Qadan (Illumina) Tr. 4278).

5839. Illumina did not estimate a figure for how payer adoption outside the United States would impact market access in the United States. (Qadan (Illumina) Tr. 4278).

5840. Dr. Carlton testified that he is not the source of any claim that Illumina will accelerate international testing and expansion of Galleri. (RX6000 (Carlton Trial Dep. at 130)).

5841. Dr. Carlton testified that he did not quantify the benefit of acceleration of international testing and expansion of Galleri in his report. (RX6000 (Carlton Trial Dep. at 130)).

5842. Dr. Carlton testified that he did not estimate any costs associated with Illumina and Grail trying to accelerate international testing and expansion of Galleri. (RX6000 (Carlton Trial Dep. at 130)).

b) Acceleration of Other Test Developers' FDA Approval Processes Is Not Verifiable or Merger Specific

5843. When Illumina previously decided to divest its interest in Grail, 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, et. al, Illumina, attaching Illumina/Grail Q&A, Jan. 2, 2017)).

5844. Dr. Carlton testified that he did not quantify the efficiency related to acceleration of other test developers' FDA approval processes. (PX7134 (Carlton Dep. at 169-70).

c) Claimed Machine Learning Efficiencies Are Not Verifiable or Merger Specific

5845. Dr. Carlton testified that he did not quantify the machine learning efficiency in his report. (PX7134 (Carlton Dep. at 167-68)).

5846. Dr. Carlton testified that he did not quantify how much the acceleration of Grail's sales may improve the accuracy of Grail's assay. (PX7134 (Carlton Dep. at 169)).

5847. Dr. Carlton testified that he did not identify which additional types of cancer may be detected through acceleration of Grail's sales. (PX7134 (Carlton Dep. at 169)).

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

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

5848. Before Illumina acquired Grail, Grail funded its operations through "private financing rounds" that involved venture capital and strategic investors. (Freidin (Grail) Tr. 3011).

5849. In addition to Illumina, Grail was previously owned by "large pharmaceutical companies" as well as mutual funds and private investors. (Bishop (Grail) Tr. 1407-08).

5850. Grail raised approximately $2 billion through its four rounds of private financing. (Freidin (Grail) Tr. 3016).

5851. As of September 2020, Grail had raised "$1.9 billion through a combination of leading venture capital and strategic partners." (PX4082 (Grail) at 086 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et. al, Morgan Stanley, attaching Grail 2020 S-1/Amended, Sept. 2020); PX5023 (Illumina) at 003 (Project: GRAIL, Phil Febbo & Corporate Development, Mar. 2020); PX6049 at 107 (Grail Narrative Response to Second Request, Mar. 1, 2021)).

5852. Grail noted in its S-1 filing that as of June 30, 2020 it "had $685.6 million in cash, cash equivalents, and marketable securities" on hand. (PX4082 (Grail) at 032 (Email from B. Cornelius, Latham & Watkins, to C. Gartin, et. al, Morgan Stanley, attaching Grail 2020 S-1/Amended, Sept. 2020)).

5853. When Grail was acquired by Illumina, Grail had over $600 million in cash. (Freidin (Grail) Tr. 3166-67).

5854. [redacted] (Ofman (Grail) Tr. 3383 (*in camera*)).

5855. Grail received investment from Jeff Bezos and Bill Gates as part of its initial Series A financing. (Freidin (Grail) Tr. 3161).

5856. In late 2016, Grail initiated its second round of financing, or Series B. (PX2552 (Illumina) at 033 (Email from A. Covington, Illumina, to F. deSouza, Illumina, attaching GRAIL Update at Illumina BoD 7-27-16 DRAFT v2, July 21, 2016)).

5857. [redacted] (PX2553 (Illumina) at 066 (Board of Directors Meeting, Oct. 2016) (*in camera*); PX7107 (deSouza (Illumina) Dep. at 209) (*in camera*)).

5858. Grail's Series B raised $1 billion between February and December of 2017 from "investors from all over the world." (Freidin (Grail) Tr. 3016-17).

5859. 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 01 (Grail Announces $300 Million Raised in Oversubscribed Series C Financing, May 21, 2018)).

5860. 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 01-02 (Grail Announces $390 Million Series D Financing, May 6, 2020)).

5861. Before accepting Illumina's acquisition offer, Grail considered pursuing additional funding through more private financing. (Freidin (Grail) Tr. 3011-12).

5862. [redacted] (PX7108 (Freidin (Grail) Dep. at 247-48) (*in camera*); PX4212 (Grail) at 008[redacted] (*in camera*); PX7066 (Freidin (Grail) IHT at 299-300) (*in camera*)).

5863. Morgan Stanley's Mr. Strom confirmed that there is significant investor interest in the cancer diagnostics space. (Strom (Morgan Stanley) Tr. 3478).

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

a) Grail Prepared to Go Public Prior to Acquisition

5864. Grail considered an initial public offering ("IPO") in 2020. (Bishop (Grail) Tr. 1325; Freidin (Grail) Tr. 3019).

5865. {[redacted]} (Freidin (Grail) Tr. 3070-71 (*in camera*); Bishop (Grail) Tr. 1407; PX7066 (Freidin (Grail) IHT at 80-81) (*in camera*)).

5866. [redacted]} (Bishop (Grail) Tr. 1437 (*in camera*); Freidin (Grail) Tr. 3020; PX7108 (Freidin (Grail) Dep. at 54-55) (*in camera*); PX4137 (Grail) at 007-08 (The Roundtable, Sept. 30, 2020) (*in camera*)).

5867. [redacted] (PX7108 (Freidin (Grail) Dep. at 25-26) (*in camera*)).

5868. Mr. Freidin testified at trial that Grail's IPO would have given Grail the capital to invest in commercialization, lab operations, and international expansion. (Freidin (Grail) Tr. 3021).

5869. As part of Grail's pursuit of an IPO, Grail created and filed a Form S-1 with the Securities and Exchange Commission on September 9, 2020. (Bishop (Grail) Tr. 1326-27; PX0043 (Grail SEC Form S-1 Registration Statement, Sept. 9, 2020)).

5870. [redacted] (PX7066 (Freidin (Grail) IHT at 63) (*in camera*)).

5871. Grail filed an Amended S-1 on September 17, 2020, after making its initial S-1 filing with the SEC. (Bishop (Grail) Tr. 1328; PX4082 (Grail) at 005 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

5872. Grail hired bankers to facilitate its IPO. (Freidin (Grail) Tr. 3019).

5873. In preparation for its IPO, Grail's executive team participated in a number of meetings with a range of potential investors over a couple months. (Bishop (Grail) Tr. 1325; Freidin (Grail) Tr. 3019).

5874. Grail's top executives, including Hans Bishop, Josh Ofman, Matthew Young, Aaron Freidin, and Arash Jamshidi participated in investor meetings leading up to its planned IPO. (Bishop (Grail) Tr. 1326).

5875. [redacted] (PX7108 (Freidin (Grail) Dep. at 30) (*in camera*)).

5876. Grail participated in non-deal roadshow ("NDR") meetings with potential IPO investors. (Bishop (Grail) Tr. 1325).

5877. After the NDR meetings, Grail participated in testing-the-waters ("TTW") meetings with potential IPO investors. (Bishop (Grail) Tr. 1325-26). The TTW meetings took place around July and August of 2020. (Bishop (Grail) Tr. 1326).

5878. Grail CEO Hans Bishop participated in many of Grail's NDR and TTW meetings with potential IPO investors. (Bishop (Grail) Tr. 1325-26).

5879. [redacted] (PX4234 (Grail) at 010 [redacted] (*in camera*); PX7108 (Freidin (Grail) Dep. at 119-20) (confirming PX4234 (Grail) captured Grail's IPO timeline)).

5880. [redacted] (PX4234 (Grail) at 010 [redacted]

[redacted] (*in camera*); PX7108 (Freidin (Grail) Dep. at 119) (testifying that if October 6 is the pricing date then Grail would "probably trade" on October 8)).

5881. Mr. Bishop confirmed at trial that the choice Grail was facing in 2020 was either to be acquired by Illumina or proceed with an IPO. (Bishop (Grail) Tr. 1408; PX7069 (Bishop (Grail) IHT at 216)). Mr. Bishop testified that both options "were evaluated in parallel over several months." (Bishop (Grail) Tr. 1408; PX7066 (Freidin (Grail) IHT at 29-30) (testifying that the IPO and Illumina deal was a "dual-track process")).

5882. [redacted] (Freidin (Grail) Tr. 3071 (*in camera*)).

5883. Because Illumina and Grail entered into an acquisition agreement, Grail never went public. (PX7108 (Freidin (Grail) Dep. at 113)).

b) [redacted]

5884. [redacted] (Freidin (Grail) Tr. 3090 (*in camera*)).

5885. [redacted] (Freidin (Grail) Tr. 3090 (*in camera*)).

5886. [redacted] (Freidin (Grail) Tr. 3090-91 (*in camera*); PX7108 (Freidin (Grail) Dep. at 21) ("[T]he market was ripe. There were a lot of favorable IPOs that were happening. . . . And [comparable companies'] values and their IPOs and their performance were all positive.")).

5887. [redacted] (Freidin (Grail) Tr. 3092 (*in camera*); PX7108 (Freidin (Grail) Dep. at 22) ("[The year 2020] was a good market for raising capital publicly.")).

5888. [redacted] (Freidin (Grail) Tr. 3091 (*in camera*)).

5889. [redacted] (Freidin (Grail) Tr. 3091-92 (*in camera*)).

5890. [redacted] (Freidin (Grail) Tr. 3092 (*in camera*)).

c) [redacted]}

5891. [redacted] (PX7108 (Freidin (Grail) Dep. at 84-85); PX7066 (Freidin (Grail) IHT at 29-30) (*in camera*)).

5892. [redacted] (PX7066 (Freidin (Grail) IHT at 30) (*in camera*)).

5893. [redacted]} (PX7066 (Freidin (Grail) IHT at 88) (*in camera*)).

d) Grail's S-1 Explains How Grail Intended to Use the Proceeds from Its IPO

5894. [redacted] (PX4137 (Grail) at 007 (The Roundtable, Sep. 30, 2020) (*in camera*); PX7066 (Freidin (Grail) IHT at 63) (*in camera*)).

5895. Grail's Amended Form S-1 lists the "principal purposes" of Grail's IPO as follows:

> The principal purposes of this offering are to obtain additional capital to fund our research and product development, create a public market for our common stock, facilitate our future access to the public equity markets, increase awareness of our company among potential partners, and improve our competitive position. We intend to use the net proceeds of this offering for development and commercialization of Galleri and DAC, development of additional products, scaling of our technology and laboratory operations, and general corporate purposes.
>
> We currently expect to use the net proceeds from this offering, together with our existing cash, cash equivalents, and marketable securities, as follows:
>
> •approximately $[blank] million to fund our clinical studies through the initial commercialization of Galleri and DAC as LDTs, and to fund ongoing and new clinical studies to validate and demonstrate the utility of our products, and support our reimbursement efforts;
>
> •approximately $[blank] million for current and future product development, including expansion of our laboratory operations to support future growth;
>
> •approximately $[blank] million for preparation for commercial launch and expansion of commercial operations, including the growth of our sales force within the United States; and

> •any proceeds not applied to the foregoing for working capital and general corporate purposes.

(PX4082 (Grail) at 075 (Email attaching Grail 2020 S-1/Amended, Sept. 2020)).

5896. The SEC sent Grail a letter on August 24, 2020 with comments to Grail's confidential S-1. (PX4099 (Grail) at 277 (Email attaching Grail 2020 S-1, Sept. 9, 2020)).

5897. The SEC provided the following comment to Grail's Use of Proceeds section of Grail's then-confidential Form S-1:

> Please revise to disclose an estimate of how far in your development and commercialization of Galleri and DAC and the development of additional products the proceeds from this offering will allow you to reach with respect to each product candidate, including specific phases of pre-clinical and clinical trials. Also, please disclose the total estimate cost of each of the specified purposes for which the net proceeds are intended to be used, and, if material amounts of other funds are necessary to accomplish the specified purposes, provide an estimate of the amounts of such other funds and the sources thereof.

(PX4099 (Grail) at 281 (Email attaching Grail 2020 S-1, Sept. 9, 2020)).

5898. In response to the SEC's comment to the "Use of Proceeds" section, Grail responded that it "does not anticipate that material amounts of other funds will be necessary to accomplish the specified purposes" in the "Use of Proceeds" section. (PX4099 (Grail) at 281 (Email attaching Grail 2020 S-1, Sept. 9, 2020)).

5899. When asked how Grail would use IPO proceeds that exceeded Grail's expectations, Mr. Freidin testified as Grail's 30(b)(6) designee that Grail would follow its LRP and "having extra cash is always good for – to be opportunistic" for "acquisitive-type transactions" outside Grail's three products. (PX7108 (Freidin (Grail) Dep. at 98-99)).

5900. At his deposition, Mr. Freidin testified that the S-1's "[U]se of [P]roceeds section was derived from the LRP." (PX7108 (Freidin (Grail) Dep. at 86)).

e) <u>During the IPO Process, Morgan Stanley Was a Trusted Advisor to Grail's Board</u> [redacted]

5901. [redacted] (Freidin (Grail) Tr. 3092 (*in camera*)).

5902. [redacted] (Bishop (Grail) Tr. 1449 (*in camera*)).

5903. [redacted] (Freidin (Grail) Tr. 3094 (*in camera*)).

5904. [redacted] (PX4137 (Grail) at 008 (The Roundtable, Sept. 30, 2020 (*in camera*)); PX7108 (Freidin (Grail) Dep. at 54-55) (*in camera*)).

5905. [redacted] (Freidin (Grail) Tr. 3095 (*in camera*)).

5906. [redacted] } (Freidin (Grail) Tr. 3096 (*in camera*); *see, e.g.,* PX4047 (Grail) at 051 (Email from M. Song, Grail, to H. Bishop, Grail, et al., attaching "Morgan Stanley Discussion Materials: Project Valor," Sept. 16, 2020 (*in camera*)).

5907. [redacted] (PX5046 (Grail) at 002 [redacted] (*in camera*)).

5908. [redacted] } (PX5046 (Grail) at 002 [redacted] (*in camera*)).

5909. [redacted] } (PX5046 (Grail) at 002 [redacted] (*in camera*)).

5910. [redacted] (Bishop (Grail) Tr. 1450-51 (*in camera*)).

5911. [redacted] (Bishop (Grail) Tr. 1451 (*in camera*)).

5912. [redacted] (Bishop (Grail) Tr. 1451 (*in camera*)).

5913. [redacted] (PX5046 (Grail) at 002 [redacted] (*in camera*)).

5914. [redacted] (Freidin (Grail) Tr. 3097 (*in camera*)).

f) [redacted]

5915. Grail's Chief Medical Officer, Dr. Josh Ofman, testified at trial that "the valuation of the company [Grail] that some of the investors and analysts were ascribing was quite high." (Ofman (Grail) Tr. 3283).

5916. At trial, Dr. Ofman described Grail's IPO as "perhaps being a more lucrative venture" than being acquired by Illumina. (Ofman (Grail) Tr. 3283).

5917. [redacted] (Bishop (Grail) Tr. 1457-58 (*in camera*): PX5045 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5918. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*); PX4175 (Grail) (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5919. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*)).

5920. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*)).

5921. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5922. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5923. [redacted] (PX7066 (Freidin (Grail) IHT at 68) (*in camera*)).

5924. [redacted] (PX7066 (Freidin (Grail) IHT at 68-69) (*in camera*)).

5925. Mr. Bishop testified at trial that "particular[] investors that had a long-term investment horizon . . . were really interested in our story. And I believe we had the potential of getting their support had we gone ahead with an IPO." (Bishop (Grail) Tr. 1410).

5926. [redacted] (Bishop (Grail) Tr. 1458 (*in camera*): PX5045 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5927. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*); PX7066 (Freidin (Grail) IHT at 66-67) (*in camera*) ([redacted])).

5928. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5929. [redacted] (PX7066 (Freidin (Grail) IHT at 68) (*in camera*)).

5930. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5931. [redacted] (Bishop (Grail) Tr. 1457 (*in camera*): PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5932. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5933. [redacted] (PX5045 (Grail) at 029 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5934. [redacted] (Bishop (Grail) Tr. 1458-59 (*in camera*): PX5045 (Grail) at 030 (Grail

Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)). [redacted] (Bishop (Grail) Tr. 1459 (*in camera*)).

5935. [redacted] (PX5045 (Grail) at 030 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5936. In an email to Grail's General Counsel, Ms. Song, Mr. Freidin described Grail's non-deal roadshow and testing-the-waters meetings as "[s]uccessful." (PX4088 (Grail) (Email from A. Freidin, Grail, to M. Song, Grail, Nov. 10, 2020). Regarding this statement in PX4088, Mr. Freidin testified that, "Yeah, it says 'successful,' meaning we met with enough of the folks that we wanted to. We were able to get feedback back from them. The analysts day, we were able to educate across many meetings how they should be thinking about our business in the long term. So it's those distinct pieces of the IPO process were successful." (PX7066 (Freidin (Grail) IHT at 203)).

5937. [redacted] (Freidin (Grail) Tr. 3098 (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5938. [redacted] (Freidin (Grail) Tr. 3098 (*in camera*)).

5939. [redacted] (PX7066 (Freidin (Grail) IHT at 69-70) (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5940. [redacted] (Freidin (Grail) Tr. 3098-99 (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5941. [redacted] (PX7066 (Freidin (Grail) IHT at 71-72) (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5942. [redacted] (PX7066 (Freidin (Grail) IHT at 71-72) (*in camera*)).

5943. [redacted] (Freidin (Grail) Tr. 3099 (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5944. {[redacted]} (Freidin (Grail) Tr. 3099 (*in camera*); PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5945. {[redacted]} (Freidin (Grail) Tr. 3099; PX4175 (Grail) at 031 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5946. [redacted]} (Freidin (Grail) Tr. 3099-100; PX4175 (Grail) at 032 (Grail Board Session Meeting Materials, Sept. 10, 2020)). (*in camera*)).

5947. [redacted] (Freidin (Grail) Tr. 3100 (*in camera*); PX4175 (Grail) at 032 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5948. [redacted] (Freidin (Grail) Tr. 3099 (*in camera*)); PX4175 (Grail) at 032 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5949. [redacted] (PX7066 (Freidin (Grail) IHT at 77) (*in camera*); PX4175 (Grail) at 032 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5950. [redacted]} (Freidin (Grail) Tr. 3099 (*in camera*); PX4175 (Grail) at 032 (Grail Board Session Meeting Materials, Sept. 10, 2020) (*in camera*)).

5951. [redacted]

[redacted]

(PX7066 (Freidin (Grail) IHT at 77) (*in camera*)).

5952. [redacted] (Freidin (Grail) Tr. 3096 (*in camera*); *see* PX7108 (Freidin (Grail) Dep. at 54-55) (testifying that Grail expected to raise between $500 and $750 million through its IPO)).

g) [redacted]

For evidence that Grail management has hit strategic targets without Illumina's assistance, see Section VIII.C.1.b.2.e.ix. (Grail Is Hitting Its Strategic Targets Toward the Commercialization of Galleri Without Illumina's Assistance).

5953. [redacted] } (PX4213 (Grail) at 00 [redacted]

5954. [redacted] (PX4213 (Grail) at 011 [redacted] *see* PX4088 (Grail [redacted]

5955. [redacted] } (Freidin (Grail) Tr. 3102-103 (*in camera*)); PX4213 (Grail) at 011 [redacted]

5956. [redacted] (Freidin (Grail) Tr. 3103 (*in camera*)).

5957. { [redacted] } (PX4213 (Grail) at 011 [redacted]

5958. [redacted] } (Freidin (Grail) Tr. 3102 (*in camera*)).

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

5959. 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)).

5960. Grail's Vice President 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).

5961. Mr. Freidin testified that, even after signing the deal with Illumina, Grail did not withdraw its Form S-1 in case it needed to go public if the Illumina deal did not finalize. (PX7108 (Freidin (Grail) Dep. at 113-14)).

5962. Grail had not withdrawn its Form S-1 as of June 23, 2021 because "if we keep this version up that [the SEC has] already reviewed, there is a chance that [the SEC does not] take 30 days to review it the next time if the [Illumina] deal does not happen." (PX7108 (Freidin (Grail) Dep. at 114)).

4. [redacted]

5963. [redacted] (Freidin (Grail) Tr. 3072 (*in camera*)).

5964. [redacted] (Freidin (Grail) Tr. 3072 (*in camera*)).

5965. [redacted] (Freidin (Grail) Tr. 3073-74 (*in camera*)).

5966. 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. 3447-48).

IX. APPENDIX A: WITNESS BACKGROUNDS

A. LAY WITNESSES WHO TESTIFIED AT TRIAL

1. Dr. Christoph Lengauer

5967. Dr. Christoph Lengauer is a co-founder of Thrive Earlier Detection, which is now owned by Exact Sciences. Dr. Lengauer is currently a partner at Third Rock Ventures, a venture fund that invests mainly in companies that the fund creates and builds themselves. (Lengauer (Third Rock Ventures) Tr. 155-57).

5968. Dr. Lengauer serves as a consultant to Exact Sciences and, in this role, oversees Thrive's strategy. As part of his responsibilities, he serves on Thrive's management leadership team and is involved in the development of the CancerSEEK test. (Lengauer (Third Rock Ventures) Tr. 156-57).

5969. Prior to the Thrive's acquisition by Exact Sciences, Dr. Lengauer was the Chief Innovation Officer of Thrive since the company was founded, overseeing the development of Thrive's CancerSEEK blood-based test and was involved in decision-making and regulatory strategy. (Lengauer (Third Rock Ventures) Tr. 157).

5970. Before serving as a partner of Third Rock Ventures, Dr. Lengauer was the Chief Scientific Officer at Blueprint Medicines, which is a biotech company focused on oncology drug discovery. Before that role, Dr. Lengauer was the Global Head of Oncology Research for Sanofi. (Lengauer (Third Rock Ventures) Tr. 158). Dr. Lengauer led the target identification and validation group of Novartis before transitioning to the role at Sanofi. (PX7051, Lengauer (Third Rock Ventures) IHT at 14).

5971. Dr. Lengauer has a Ph.D. in biology from the University of Heidelberg (Germany) and has a Master of Business Administration degree from Johns Hopkins University. In addition, Dr. Lengauer currently is an adjunct associate professor at Johns Hopkins University. (Lengauer (Third Rock Ventures) Tr. 158).

5972. Dr. Lengauer completed postdoctoral training at Johns Hopkins University with the laboratory of Bert Vogelstein and Ken Kinzler. Following this training, Dr. Lengauer worked in this laboratory developing a greater understanding of the nature of genetics and cancer for approximately ten years. (PX7051 (Lengauer (Third Rock Ventures) IHT at 13-14)).

2. Dr. Matthew Rabinowitz

5973. Dr. Matthew Rabinowitz is the co-founder of Natera and is currently Executive Chairman of the company, serving in this role since 2019. (Rabinowitz (Natera) Tr. 284-86). As Executive Chairman of Natera, Dr. Rabinowitz oversees development and strategy related to Natera's technology and business development decisions. (Rabinowitz (Natera) Tr. 286). Further, as Executive Chairman, Dr. Rabinowitz oversees regulatory decisions and activities, but is less involved compared to when he was the Chief Executive Officer of the company. (Rabinowitz (Natera) Tr. 296). {[redacted]

[redacted]
(PX7054 (Rabinowitz (Natera) IHT at 20-21 (*in camera*))).

5974. Prior to serving as Executive Chairman of Natera, Dr. Rabinowitz was the Chief Executive Officer of the company. (Rabinowitz (Natera) Tr. 285). As Natera's CEO, Dr. Rabinowitz was directly involved in the day-to-day operations of the company. (Rabinowitz (Natera) Tr. 286-87). [redacted] (PX7054 (Rabinowitz (Natera) IHT at 19 (*in camera*))). [redacted] (PX7054 (Rabinowitz (Natera) IHT at 19 (*in camera*))).

5975. [redacted] (PX7054, Rabinowitz (Natera) IHT at 19 (*in camera*)).

5976. Dr. Rabinowitz has a Ph.D. in electrical engineering from Stanford University, as well as a B.S. and M.S. in electrical engineering from Stanford. (Rabinowitz (Natera) Tr. 284). In addition, Dr. Rabinowitz was a consulting professor at Stanford for eight years in the School of Engineering. (Rabinowitz (Natera) Tr. 287). He was also a visiting faculty member at Harvard University in the Genetics Department. (Rabinowitz (Natera) Tr. 287; PX7113 (Rabinowitz Depo at 55)).

3. Dr. William Cance

5977. Dr. William Cance is the Chief Medical and Scientific Officer of the American Cancer Society, serving in this role since October 2019. (Cance (American Cancer Society) Tr. 591-92).

5978. As the Chief Medical and Scientific Officer of ACS, Dr. Cance's responsibilities include overseeing the medical and scientific aspects of the ACS's mission programs, such as its efforts in discovery, research, the development of patient programs implementation science, as well as providing advice and oversight of programs across the ACS's mission pillars. (Cance (American Cancer Society) Tr. 592).

5979. Dr. Cance testified at trial that the ACS has three mission pillars: "advocacy, discovery, and patient support." (Cance (American Cancer Society) Tr. 592). Advocacy includes public policy; discovery includes research that the ACS does that the organization funds externally, and patient support includes providing rides, lodging, and work with health systems across the United States. (Cance (American Cancer Society) Tr. 592-93).

5980. Dr. Cance is a licensed physician with clinical expertise in surgical oncology. (Cance (American Cancer Society) Tr. 593). Dr. Cance has been a licensed physician since 1982. (Cance (American Cancer Society) Tr. 593).

5981. Prior to his role at ACS, Dr. Cance was the deputy director and interim director of the University of Arizona Cancer Center in Phoenix, Arizona, where he coordinated cancer

efforts while the University of Arizona expanded from Tucson into Phoenix and also oversaw an active research laboratory at the University of Arizona College of Medicine. (Cance (American Cancer Society) Tr. 594). While at the University of Arizona, Dr. Cance taught surgery and supervised surgical residents at Dignity Health St. Joseph's Hospital and was a Professor of Interdisciplinary Oncology. (Cance (American Cancer Society) Tr. 594).

5982. Dr. Cance is not currently employed by or being compensated by any company that is developing an early cancer detection test. (Cance (American Cancer Society) Tr. 597).

5983. Dr. Cance received his M.D. from Duke University School of Medicine and completed his residency at Barnes-Jewish Hospital in St. Louis, Missouri. (Cance (American Cancer Society) Tr. 593). In addition he completed a fellowship in immunology at Washington University School of Medicine in St. Louis, which is the academic partner of Barnes-Jewish Hospital. (Cance (American Cancer Society) Tr. 593-94). Dr. Cance also completed a clinical fellowship in surgical oncology at Memorial Sloan Kettering Cancer Center in New York. (Cance (American Cancer Society) Tr. 594).

4. Dr. Kenneth Chahine

5984. Dr. Ken Chahine was the Chief Executive Officer of Helio Health, Inc. ("Helio") from January 2020 to June 2021. (Chahine (Helio) Tr. 999). As Helio's CEO, Dr. Chahine essentially ran "all operations at the company." (Chahine (Helio) Tr. 999-1000).

5985. Since departing as CEO in June 2021, Dr. Chahine is now a consulting advisor to Helio, including an advisor specifically to Helio's CEO and its Board of Directors, when requested. (Chahine (Helio) Tr. 999).

5986. Dr. Chahine received a Ph.D. in biological chemistry from the University of Michigan, in which the focus of his thesis was on genetics and molecular biology. (Chahine (Helio) Tr. 1008-09). Dr. Chahine earned a juris doctorate as well and is a registered patent attorney. (Chahine (Helio) Tr. 1009).

5. Dr. Darya Chudova

5987. Dr. Darya Chudova is the Senior Vice President of Technology at Guardant Health ("Guardant") and has been in this role for approximately three years. (Chudova (Guardant) Tr. 1136). Prior to this role, she served as a Vice President of Technology and Senior Director of Bioinformatics at Guardant. (Chudova (Guardant) Tr. 1136). Dr. Chudova began working at Guardant in 2015. (Chudova (Guardant) Tr. 1135).

5988. Dr. Chudova's responsibilities as Guardant's Senior Vice President of Technology include overseeing technology development projects, such as the development of clinical diagnostic tests for therapy selection and MRD. (Chudova (Guardant) Tr. 1137-38).

5989. Until shortly before she testified at trial, Dr. Chudova was responsible for the entire technology staff at Guardant. (Chudova (Guardant) Tr. 1137).

5990. Dr. Chudova is currently focused on the development of Guardant's cancer screening applications. (Chudova (Guardant) Tr. 1137).

5991. Dr. Chudova testified at trial that she has been "very intrinsically involved" with the R&D teams at Guardant during her time at the company, including ensuring the "next-generation sequencing component" of its clinical diagnostic tests work and are "fit[ ] for the purpose of what [Guardant is] developing." (Chudova (Guardant) Tr. 1138-40). Each of Guardant's clinical tests in development uses NGS sequencing in its workflow. (Chudova (Guardant) Tr. 1140).

5992. Dr. Chudova was involved in the process of obtaining FDA approval for Guardant's Guardant360 therapy selection test. (Chudova (Guardant) Tr. 1149). Dr. Chudova testified at trial that she was "intimately involved in both the internal development work, as well as validation work leading up to the submission and [Guardant's] defense of the regulatory filing" with the FDA for the Guardant360 test. (Chudova (Guardant) Tr. 1149).

5993. Prior to her work at Guardant, Dr. Chudova served from 2008 to 2013 as a data analysis computational science contributor at Veracyte, which is a clinical diagnostic company focused on developing technologies related to thyroid cancer. (Chudova (Guardant) Tr. 1142-43). Dr. Chudova's work at Veracyte involved the use of micro-array technology. (Chudova (Guardant) Tr. 1142-43).

5994. Starting in early 2013, Dr. Chudova began working at Verinata, a company that was developing NIPT products reliant on NGS technology and was acquired by Illumina soon after she began working there. (Chudova (Guardant) Tr. 1143-44). After the acquisition, Dr. Chudova served as Associate Director of Bioinformatics at Illumina. (Chudova (Guardant) Tr. 1144).

5995. Dr. Chudova served as Associate Director of Bioinformatics at Illumina from early 2013 to 2015, where she focused on NIPT products. (Chudova (Guardant) Tr. 1144-45). While at Illumina, Dr. Chudova helped publish articles related to NIPT and the potential use of the technology for the early detection of cancer. (Chudova (Guardant) Tr. 1145-46).

5996. Dr. Chudova testified at trial that she left Illumina for Guardant in 2015 because she "was excited to find a company that was focused on applying" liquid biopsy technologies "that would be helpful for cancer patients." (Chudova (Guardant) Tr. 1146).

5997. Dr. Chudova received a master's degree in applied mathematics in Russia. (Chudova (Guardant) Tr. 1141). Dr. Chudova received a Ph.D. in computer science in the United States in 2007, which included three years of study in a joint program between the computer science and molecular biology departments to obtain a specialty in bioinformatics. (Chudova (Guardant) Tr. 1141-42).

6. Kevin Conroy

5998. Kevin Conroy is the Chairman and Chief Executive Officer of Exact Sciences ("Exact") and has worked at the company for over twelve years. (Conroy (Exact) Tr. 1526). Mr.

Conroy joined the company on April 2, 2009, and at that time, there were only three employees including himself. (Conroy (Exact) Tr. 1532).

5999. Mr. Conroy testified at trial that when he joined the company, they had the "idea" to "develop two things, a colon cancer screening test that allows you to accurately detect colon cancer through a sample collected in the privacy of your own home[;] [a]nd then secondly, long-term was to develop what then we called a pan-cancer screening test or a universal cancer screening test from a single blood draw." (Conroy (Exact) Tr. 1532).

6000. Under Mr. Conroy's leadership, Exact has grown from a small, pre-commercial company into having approximately 6,000 employees and offering a range of different tests that are now sold to physicians and patients; as Mr. Conroy testified at trial, Exact is a "commercial company in that we have teams of people who educate healthcare providers about the tests that we offer, and we provide clinical testing services." (Conroy (Exact) Tr. 1532-33).

6001. As Chairman and CEO of Exact, Mr. Conroy's responsibilities include setting the agenda of the board of directors and general responsibility for the operations of the company. (Conroy (Exact) Tr. 1527).

6002. As CEO, Mr. Conroy has responsibility for strategic planning for the company, including the annual planning process, the three-year plan, the five-year plan, and more generally, "planning for how you can screen more people to detect cancer early and all of the investments and people that you need to make that happen." (Conroy (Exact) Tr. 1527). As part of the strategic planning process, Mr. Conroy assesses "internal and external threats" that could affect the company's "ability to make that long-term plan become real." (Conroy (Exact) Tr. 1527-28).

6003. As Chairman and CEO of Exact, Mr. Conroy has responsibilities relating to the merger and acquisition strategy of the company. (Conroy (Exact) Tr. 1528).

6004. Mr. Conroy is responsible for the overall commercialization of Exact's products, including ensuring that Exact brings their tests to physicians, healthcare providers, and ultimately to patients. (Conroy (Exact) Tr. 1529).

6005. Mr. Conroy is generally familiar with the commercialization planning for Exact's cancer tests. (Conroy (Exact) Tr. 1529).

6006. As Chairman and CEO of Exact, Mr. Conroy typically is not involved in negotiating supply contracts, but has been involved in "a very limited number of cases, including involved to a certain extent in negotiating or having conversations with Illumina because of the critical nature of next-generation sequencing as part of our long-term plan." (Conroy (Exact) Tr. 1528-29).

6007. Mr. Conroy consults Dr. Lengauer of Thrive when he has questions about CancerSEEK's technical specifications. (Conroy (Exact) Tr. 1553-54).

6008. Mr. Conroy received a juris doctorate from the University of Michigan in 1991. (Conroy (Exact) Tr. 1530). Mr. Conroy practiced intellectual property law for approximately nine

years in private practice and then in-house counsel for several years after that. (Conroy (Exact) Tr. 1530). Mr. Conroy was a member of the patent bar. (Conroy (Exact) Tr. 1530).

7. Dr. Andy Felton

6009. Dr. Andy Felton is the Vice President of Product Management, Platform Research, and Applied Markets at Thermo Fisher Scientific ("Thermo") and has served in this role for approximately seven years and with the legacy business for ten years. (Felton (Thermo Fisher) Tr. 1978-79).

6010. As the Vice President of Product Management, Platform Research, and Applied Markets at Thermo, Dr. Felton is responsible for the company's next-generation sequencing platforms (e.g., Ion Torrent), reagents, and software within the Clinical Sequencing Division as well as applications in research and applied markets. (Felton (Thermo Fisher) Tr. 1979).

6011. As part of his responsibilities, Dr. Felton monitors Thermo's competitors in the next-generation sequencing market and he understands the technology of their competitors as well as the requirements of the company's customers. (Felton (Thermo Fisher) Tr. 1980).

6012. Prior to his current position at the company, Dr. Felton was the Senior Director of Product Management for Thermo's Next-Gen Sequencing Division from 2010 to 2014. (Felton (Thermo Fisher) Tr. 1980). In this role, Dr. Felton had very similar responsibilities to his current role in that he oversaw the next-generation sequencing platforms of the company as well as the core reagents. (Felton (Thermo Fisher) Tr. 1980).

6013. Before working at Thermo, Dr. Felton was the Director of Product Management for the capillary electrophoresis sequencing business at Applied Biosciences. (Felton (Thermo Fisher) Tr. 1980-81). In that role, Dr. Felton was responsible for platforms and core reagents of the capillary sequencing business, which was a precursor technology to next-generation sequencing. (Felton (Thermo Fisher) Tr. 1981). At Applied Biosciences, Dr. Felton was also involved in product management for the real-time PCR, sample preparation, and DNA synthesis businesses. (Felton (Thermo Fisher) Tr. 1981). Dr. Felton started at Applied Biosciences in 1994 and worked there until joining Thermo. (Felton (Thermo Fisher) Tr. 1981).

6014. Dr. Felton has a B.S. in chemistry from John Moores University as well as a Ph.D. in peptide protein chemistry from Oxford Brooks University. (Felton (Thermo Fisher) Tr. 1981).

8. William John Tolan Getty, III

6015. William Getty is the Senior Vice President of Commercial for the Screening Division at Guardant Health ("Guardant"). (Getty (Guardant) Tr. 2482). Mr. Getty has been in this role since January 2021. (Getty (Guardant) Tr. 2482-83).

6016. As SVP of Commercial for Guardant's Screening Division, Mr. Getty's responsibilities include "lead[ing] the commercialization of [Guardant's] screening product in

development," the LUNAR-2, which "encompasses sales, marketing, medical affairs, commercial development, [and] all manners of activities that will support the commercialization of the product." (Getty (Guardant) Tr. 2483).

6017. In this role as SVP of Commercial, Mr. Getty "interact[s] with the broader organization on a strategic basis" regarding the development of Guardant's cancer screening tests. (Getty (Guardant) Tr. 2483-84). Mr. Getty reports to the Co-CEO, AmirAli Talasaz, and spends "a lot of time talking about strategic planning" with him; Mr. Getty is also a member of the executive management team where "those discussions are happening across the broader portfolio." (Getty (Guardant) Tr. 2484-85).

6018. Mr. Getty has responsibilities relating to Guardant's competitive assessments, testifying that "pretty much everyday [in] commercialization discussions, we are thinking about what our competition is doing, and . . . constantly staying abreast of what we can in terms of the competitive environment, how they are moving, and what that means for us as an organization, either to compete, or what it frankly means about the market longer term." (Getty (Guardant) Tr. 2485-86).

6019. After Guardant commercializes its screening test, Mr. Getty "will be responsible for overseeing the execution and [Guardant's] performance relative to the uptake of the test and . . . the responsibilities around revenue generation and making sure that we are moving forward." (Getty (Guardant) Tr. 2486). In this role, it will be Mr. Getty's responsibility to ensure physician adoption of the test, that the company is meeting internal forecasts, and ensuring that Guardant has a profitable business doing these activities. (Getty (Guardant) Tr. 2486-87).

6020. Guardant's executive management team, on which Mr .Getty serves, is "made up of senior leaders within the organization," as well as the co-CEOs. (Getty (Guardant) Tr. 2487). The executive management team has the "responsibility of guiding the organization on a strategic basis," which includes decisions about mergers and acquisitions, competitive threats, as well as things affecting the broader organization. (Getty (Guardant) Tr. 2487).

6021. Mr. Getty interacts with Dr. Darya Chudova, who also is part of the executive management team, and "spend[s] a lot of time talking about technical development, clinical development, and . . . more broadly about the program overall." (Getty (Guardant) Tr. 2487-88).

6022. When Mr. Getty first joined Guardant, he was the Vice President of Marketing of the Oncology Division. (Getty (Guardant) Tr. 2481-82). He served in this role until becoming the SVP of Commercial for the Screening Division at Guardant. (Getty (Guardant) Tr. 2482-83).

6023. Prior to joining Guardant, Mr. Getty worked in the life sciences industry for many years, including working at Pfizer, Medivation (which was purchased by Pfizer), as well as Exelixis. (Getty (Guardant) Tr. 2481).

6024. Mr. Getty has a B.S. in biology from the University of Massachusetts at Amherst, and a Master of Business Administration from Fairleigh Dickinson University. (PX7040, Getty IHT at 13).

9. Michael Nolan

6025. Michael Nolan is the Chief Executive Officer at Freenome and has been in this role since April 2021. (Nolan (Freenome) Tr. 2695). Prior to becoming CEO, Mr. Nolan was the Chief Business Officer at Freenome from April 2019 until April 2021. (Nolan (Freenome) Tr. 2695).

6026. As Freenome's CEO, Mr. Nolan's responsibilities include managing "all functions" of the company, including product development, strategic planning, as well as the commercialization of Freenome's products. (Nolan (Freenome) Tr. 2698-701).

6027. Mr. Nolan testified that Freenome has a "technical assessment team," whose function is to "help [Freenome] evaluate different solutions [the company] might be considering, first of all starting with what are the science or the research questions that [Freenome] need[s] to be able to answer with that technology or … how [Freenome] might need to apply that technology for purposes of advancing in product development." (Nolan (Freenome) Tr. 2738-39). One area that the technical assessment team provides assessments on are NGS sequencers. (Nolan (Freenome) Tr. 2739).

6028. While serving as Freenome's Chief Business Officer, Mr. Nolan's responsibilities included various functions, such as "clinical development, market development, business development, corporate development, marketing, also IP strategy, and then additionally with the responsibility to look forward to additional functions that we'll have with sales, client services, [and] payer relations." (Nolan (Freenome) Tr. 2695-96). As part of his responsibilities with business development, Mr. Nolan was involved with the team that focuses on developing collaborations or partnerships. (Nolan (Freenome) Tr. 2696). As part of his responsibilities with market development, Mr. Nolan was involved with "forming relationships with key opinion leaders" as well as sites that assist Freenome with their ongoing clinical trial. (Nolan (Freenome) Tr. 2696-97).

6029. Prior to serving as Freenome's Chief Business Officer, Mr. Nolan was Freenome's Chief Commercial Officer. (Nolan (Freenome) Tr. 2697). In this role, Mr. Nolan's responsibilities involved "defining the customer requirements and then establishing the product requirements for [Freenome] to use in setting product specifications for the work that [they] would do to develop a test that would be brought to market." (Nolan (Freenome) Tr. 2697).

6030. Mr. Nolan "started in the industry in 1992," and "held a number of different roles through that process of increasing responsibility across various functions, including sales, marketing, market development, business development, general management, ranging from companies like Abbott Diagnostics to Roche Molecular Diagnostics to Life Technologies, Thermo Fisher, Luminex, [and] Foundation Medicine." (Nolan (Freenome) Tr. 2701).

6031. Mr. Nolan worked at Thermo Fisher from 2012 to 2015 as the Vice President and General Manager for Global Oncology. (Nolan (Freenome) Tr. 2701-02). In this role, Mr. Nolan's responsibilities included "taking the assets that the company had," such as their various instruments and platforms along with the consumables and service models oriented towards research use, and "bringing those to the category of oncology." (Nolan (Freenome) Tr. 2702). While at Thermo Fisher, Mr. Nolan worked with the PGM Dx next-generation sequencer. (Nolan (Freenome) Tr. 2702-03).

6032. Mr. Nolan has a B.S. in biological sciences and secondary education, as well as a Master of Business Administration from the University of Wyoming. (PX0042 at 003 (Michael Nolan, LinkedIn Profile)).

10. Dr. Gary Gao

6033. Dr. Gary Gao is a founder and Chief Executive Officer of Med Data Quest, which is part of Singlera Genomics ("Singlera"). (Gao (Singlera) Tr. 2860). Dr. Gao is a board member, co-founder, and scientific advisor of Singlera. (Gao (Singlera) Tr. 2860).

6034. When Dr. Gao co-founded Singlera, he was the chairman of the board, scientific advisor, and the president of U.S. operations. (Gao (Singlera) Tr. 2870-71). Dr. Gao's responsibilities included organizing the team, overseeing the laboratory, hiring people, raising capital, etc. (Gao (Singlera) Tr. 2871). Dr. Gao served as chairman of the board of Singlera from July 2014 until June 2020. (Gao (Singlera) Tr. 2871-72).

6035. Since June 2020, Dr. Gao has remained a board member and scientific advisor of Singlera. (Gao (Singlera) Tr. 2872). In these roles, Dr. Gao is involved in "any technology discussion with investors" as well as giving lectures, attending meetings to provide scientific input, and publishing papers. (Gao (Singlera) Tr. 2872).

6036. With respect to the development of Singlera's products, Dr. Gao is currently a scientific advisor and "heavily involved in the research part"; Dr. Gao meets weekly with Singlera's Chief Technology Officer Dr. Rui Lui as well as Professor Kun Zhang, who is another co-founder and scientific advisor of Singlera. (Gao (Singlera) Tr. 2871). In these discussions, Dr. Gao testified that they discuss the "research direction and also evaluate the research, and then [they] provide papers and publish results." (Gao (Singlera) Tr. 2871).

6037. Dr. Gao obtained his bachelor's degree in biology from Beijing University in 1992, and then obtained a master's degree in biochemistry at the University of Tennessee Medical Center. (Gao (Singlera) Tr. 2860). Following this, Dr. Gao received a Ph.D. in computer science from the University of Memphis, and then conducted four years of Ph.D. research at IBM T.J. Watson Research in New York City. (Gao (Singlera) Tr. 2860).

6038. In 2006, Dr. Gao became an assistant professor at Virginia Commonwealth University in computer science, genomics, and life sciences. (Gao (Singlera) Tr. 2860-62). As an assistant professor at VCU, Dr. Gao conducted research at one of the first independent laboratories to purchase a Solexa next-generation sequencer before Illumina acquired Solexa. (Gao (Singlera) Tr. 2863).

6039. After four years as an assistant professor at VCU, Dr. Gao became an associate professor at the Lieber Institute of Brain Development at Johns Hopkins Biomedical Engineering department. (Gao (Singlera) Tr. 2860-61).

6040. In 2013, Dr. Gao left his employment as an associate professor at The Johns Hopkins University to start Med Data Quest under Singlera Genomics. (Gao (Singlera) Tr. 2861).

6041. Prior to his work at Singlera, Dr. Gao had experience with cell-free DNA. (Gao (Singlera) Tr. 2863-64). Dr. Gao's "earliest introduction into cell-free DNA work was through cooperation with Professor Dennis Lo from Chinese University of Hong Kong in 2007." (Gao (Singlera) Tr. 2863-64). Dr. Gao testified that "Professor Lo identified [him] as a collaborator" and Dr. Gao developed a protocol to process pregnant mother's blood to analyze cell-free DNA to identify whether or not the fetus had Down syndrome. (Gao (Singlera) Tr. 2864). From this research, Dr. Gao and Professor Lo published a paper in Proceedings of National Academy of Science in 2008, which described the use of cell-free DNA for non-invasive prenatal testing. (Gao (Singlera) Tr. 2864).

6042. After working with Professor Lo, Dr. Gao "figure[d] the same thing can be applied to detecting cancer." (Gao (Singlera) Tr. 2864). Dr. Gao spoke with Professor Kun Zhang at UCSD concerning this and together they started Singlera Genomics in July 2013 to use cell-free DNA to detect cancer early. (Gao (Singlera) Tr. 2864).

6043. Dr. Gao testified at trial that while he was performing research related to early cancer detection, Singlera Genomics was "way ahead of Grail," as Singlera was incorporated in July 2014 and Grail was "started as a spinoff from Illumina in 2015." (Gao (Singlera) Tr. 2869).

11. Dr. Alex Aravanis

6044. Dr. Alex Aravanis is the Chief Technology Officer at Illumina and has been in this role since June 2020. (Aravanis (Illumina) Tr. 1809-10).

6045. As Illumina's Chief Technology Officer, Dr. Aravanis is responsible for research and product development programs, develops strategies in those areas, and participates as a member of the executive team representing research and development. (Aravanis (Illumina) Tr. 1809-10).

6046. Dr. Aravanis is a co-founder of Grail and was involved in the early research and development of the technology relevant to Grail. (Aravanis (Illumina) Tr. 1772). Dr. Aravanis was also involved in preparing the business plan for Grail and the operational aspects of creating Grail as an independent company. (Aravanis (Illumina) Tr. 1772-73). Dr. Aravanis joined Grail in 2016 as Vice President of Research and Development. (Aravanis (Illumina) Tr. 1778). In this role, Dr. Aravanis developed the research and development program at Grail, as well as built and managed the research and development team. (Aravanis (Illumina) Tr. 1817).

6047. Dr. Aravanis was promoted to Chief Scientific Officer at Grail, which included all of his responsibilities as Vice President of Research and Development, as well as laboratory

operations and clinical development. (Aravanis (Illumina) Tr. 1818). Dr. Aravanis left Grail in May 2020 to join Illumina as Chief Technology Officer. (Aravanis (Illumina) Tr. 1819).

12. Hans Bishop

6048. Hans Bishop is the former Chief Executive Officer of Grail and became CEO in 2019. (Bishop (Grail) Tr. 1316; 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)). Mr. Bishop joined Grail's board of directors approximately one year before becoming CEO; he continued to serve on Grail's board of directors after becoming CEO. (Bishop (Grail) Tr. 1316).

6049. As CEO of Grail, Mr. Bishop was responsible to the board of directors and overseeing the leadership team at Grail. (Bishop (Grail) Tr. 1316-17). Further, as CEO of Grail, Mr. Bishop was responsible for proposing the company's overall strategy to the board, which would ultimately agree or reject such proposals. (Bishop (Grail) Tr. 1317). Moreover, Mr. Bishop's responsibilities included, *inter alia*, hiring and leading the management team, working with the management team to develop Grail's scientific product plans, working to finance the company, as well as report to the board of directors. (Bishop (Grail) Tr. 1317-18).

6050. As a member of Grail's board of directors, Mr. Bishop's responsibilities included, *inter alia*, ensuring that shareholders' interests were represented, that there was good discipline and processes regarding how Grail was run and controlled, and oversaw the quality of the management of the company. (Bishop (Grail) Tr. 1316). In addition, Mr. Bishop presented various aspects of Grail's business to the board of directors, including, company strategy, results from R&D and product development efforts, financials, as well as strategy to serve customers. (PX7069 (Bishop (Grail) IHT at 26-27)).

6051. When Mr. Bishop was the CEO of Grail, his management team included, among others, Joshua Ofman, Matt Young, Marissa Song, Alice Chen, and Uplaksh Kumar. (PX7069 (Bishop (Grail) IHT at 26)).

6052. Mr. Bishop was involved in Grail's potential initial public offering in 2020. (Bishop (Grail) Tr. 1325).

6053. As part of exploring an IPO, Grail engaged in a number of meetings in July and August of 2020 with a range of potential investors, and Mr. Bishop participated in a "great many of them." (Bishop (Grail) Tr. 1325-26). After engaging in these non-deal roadshow meetings, Grail engaged in a second set of meetings with possible investors called "testing the waters" meetings. (Bishop (Grail) Tr. 1325-26). As Grail's CEO, Mr. Bishop presented and "participated in many of them," as did Dr. Josh Ofman, Matthew Young, Aaron Freiden, and Arash Jamshidi. (Bishop (Grail) Tr. 1326).

6054. As part of the IPO process, Mr. Bishop testified that the process to create the Form S-1 document was "rigorous," "reviewed by internal experts at Grail," "reviewed by both

finance and legal at Grail," "reviewed by external experts," and Mr. Bishop was personally involved in preparing and reviewing the S-1. (Bishop (Grail) Tr. 1327). Mr. Bishop tried to ensure that the information contained in the S-1 was accurate, as Grail has an obligation to be truthful in the S-1. (Bishop (Grail) Tr. 1327-28).

6055. [redacted] (Bishop (Grail) Tr. 1438-39) (*in camera*)).

6056. [redacted] (Bishop (Grail) Tr. 1501-02 (*in camera*)).

6057. [redacted] (Bishop (Grail) Tr. 1501-02 (*in camera*)).

6058. [redacted] (PX4473 (Grail) at 003 (Core Team, Apr. 15, 2021) (*in camera*)).

6059. [redacted] (PX4473 (Grail) at 010 (Core Team, Apr. 15, 2021) (*in camera*)).

13. Nicole Berry

6060. Nicole Berry is Illumina's Senior Vice President and General Manager of the Americas commercial region and has been in this role since January 2020. (Berry (Illumina) Tr. 642). Prior to this role, Ms. Berry served as the Vice President of the Americas sales team. (Berry (Illumina) Tr. 642). She has been employed at Illumina since 2009. (Berry (Illumina) Tr. 642).

6061. In her role as Illumina's Senior Vice President and General Manager of the Americas commercial region, Ms. Berry is responsible for Illumina's customer-facing functions in the United States, Canada, and Latin America, which includes sales, service and support, and the commercial operations team. (Berry (Illumina) Tr. 643).

6062. The service and support function includes the installation of Illumina's equipment into laboratories, servicing Illumina's equipment, as well as technical support. (Berry (Illumina) Tr. 646).

6063. Ms. Berry testified at trial that Illumina instruments are not "plug-and-play"; Illumina conducts a "check to ensure that the [customer's] operating environment is compatible," which includes "everything from the physical space, size, ventilation, humidity temperature, you know, HVAC, all those things are compatible with the operating requirements of the specific instrumentation." (Berry (Illumina) Tr. 672-73). After the Illumina instrument arrives, Illumina uncrates the equipment, as it is "a sensitive piece of instrumentation," and "essentially fire it up, you know, we do the – a little bit of on-site

assembly, fire it up, and then we need to make sure that … it hasn't been damaged in transit, for example." (Berry (Illumina) Tr. 673). Illumina's service and support teams then "run control samples to validate that the instrument is performing to the specifications that exist for the instrument." (Berry (Illumina) Tr. 673). The whole process takes "three or four days to do[;] so it's not like plugging in a refrigerator and sticking your stuff in the fridge." (Berry (Illumina) Tr. 673-74).

6064. The commercial operations function includes administering price quotes to customers, business analytics (i.e., the collection of activities that relate to analyzing various business metrics and "how they may give [Illumina] the ability to, for example, forecast future business, provide information to other Illumina groups that is important for them to understand so that we can together work to meet the needs of our customers"). (Berry (Illumina) Tr. 646-47). In addition, Ms. Berry is responsible for the oversight of the sales leaders, the development of Illumina's sales plans and strategies, and meeting Illumina's revenue targets. (Berry (Illumina) Tr. 643).

6065. Ms. Berry's team keeps track of every product that a customer orders, the service that customers receive, and also maintain a database that includes the prices that customers pay. (Berry (Illumina) Tr. 647). Ms. Berry testified that "customer-specific information related to sales, order history, service and support" is all "confidential information." (Berry (Illumina) Tr. 647).

6066. Grail was one customer that was under Ms. Berry's responsibilities until Illumina consummated the acquisition of Grail on August 18, 2021. (Berry (Illumina) Tr. 649-50). Ms. Berry testified at trial that Illumina has "recently transitioned sales responsibility to Grail to an individual within Illumina who has no other customer responsibilities related to the oncology testing space." (Berry (Illumina) Tr. 650). When Grail was separate from Illumina prior to the acquisition, Ms. Berry had access to the prices Grail paid as well as the products that Grail purchased. (Berry (Illumina) Tr. 650).

6067. Ms. Berry testified that all customers that have shipment locations in the United States falls under her responsibilities, including Exact Sciences, Guardant Health, Natera, Freenome, Singlera, Foundation Medicine. (Berry (Illumina) Tr. 650-51).

6068. Ms. Berry has responsibilities relating to Illumina's supply agreements, testifying that she "oftentimes am called in to supply agreement discussions with customers as it relates to the terms that a customer may be seeking and our ability to accommodate those terms." (Berry (Illumina) Tr. 653). In addition, Ms. Berry provides input into the business terms of supply agreements, working closely with Illumina's legal team to translate customers' business requests into contract language. (Berry (Illumina) Tr. 653). Ms. Berry testified that she has "participated in many, many meetings prior to signature" where customers have questions on the terms of the supply agreements during the "negotiation or supply agreement development phase." (Berry (Illumina) Tr. 654).

6069. Ms. Berry testified at trial that she is familiar with the open offer that Illumina posted on its website, which is a standardized long-term supply agreement offered to Illumina's oncology customers that includes "key terms related to assuring the customer of continued

access to products, access to service, continuity, and access to commercial terms that they may have experienced prior to the acquisition." (Berry (Illumina) Tr. 688-89). In addition, Ms. Berry is "familiar with the essence of many of the negotiations" with oncology customers regarding the open offer and Ms. Berry is the signatory of the open offer, as she is the Senior Vice President responsible for the commercial business within the United States. (Berry (Illumina) Tr. 689-90).

6070. [redacted] (Berry (Illumina) Tr. 750-51 (*in camera*)).

6071. [redacted] (Berry (Illumina) Tr. 774 (*in camera*)).

6072. In a text message between Ms. Berry and Kathy Davy, Illumina's former Vice President of Marketing for Clinical Genomics, Ms. Berry responded to a question about [redacted] by stating that [redacted] (PX2283 (Illumina) at 001 (Mobile text chain between N. Berry, Illumina, and K. Davy, Illumina, June 4, 2020) (*in camera*); Berry (Illumina) Tr. 737-38 (*in camera*)).

6073. In a text message dated September 16, 2020, four days prior to the announcement of Illumina's proposed acquisition of Grail, [redacted] (PX2158 (Illumina) at 001 (Mobile text chain between N. Berry, Illumina, and J. Preston, Illumina, Sept. 16, 2020) (*in camera*); (Berry (Illumina) Tr. 743-44 (*in camera*)).

14. Chris Della Porta

6074. Chris Della Porta is Grail's Director of Growth Strategy and has been in this role since September 2020. (Della Porta (Grail) Tr. 453-54).

6075. Mr. Della Porta founded Grail's growth strategy team, which he currently leads and is involved with planning for this team. (Della Porta (Grail) Tr. 455). In his role as Director of Growth Strategy, he oversees the development of commercial forecasts for all products for long range planning and IPO efforts, as well as managing direct reports to successfully execute on model development. (PX4271 (Grail) at 001 (Della Porta Resume)).

6076. One purpose of the growth strategy team is to develop new channels for the sale of Grail's Galleri test, which includes strategically evaluating potential customers for Galleri and approaching potential partners for the sale of Galleri. (Della Porta (Grail) Tr. 455-56). These potential customers include physicians groups, health systems, and employers. (Della Porta (Grail) Tr. 456-57). In addition, [redacted]

[redacted]} (Della Porta (Grail) Tr. 527-28 (*in camera*)).

6077. Grail's growth strategy team was involved with tasks relating to the launch of Galleri, including securing initial concierge physician customers. (Della Porta (Grail) Tr. 461-62).

6078. As Grail's Director of Growth Strategy, Mr. Della Porta reports to Grail's Chief Commercial Officer Mr. Gautam Kollu. (Della Porta (Grail) Tr. 454-55).

6079. Mr. Della Porta is the Diagnostic Aid for Cancer product lead, progressing the DAC product concept to approved product program. In addition, Mr. Della Porta is the commercial lead on the new MRD concept team, responsible for commercial strategy and the business case. (PX4271 (Grail) at 001 (Della Porta Resume)).

6080. Mr. Della Porta was involved in founding Grail's competitive intelligence team, which had approximately ten people in the beginning of 2021. (Della Porta (Grail) Tr. 467). The competitive intelligence team's role included monitoring industry developments that were relevant to Grail. (Della Porta (Grail) Tr. 467). While Mr. Della Porta was the co-lead of the competitive intelligence team, it produced various work product, which included presentations and reports of particular companies and technologies of interest, and this was shared internally among Grail's executives and the board of directors. (Della Porta (Grail) Tr. 468-69). Mr. Della Porta was involved in collecting commercial information during his time on the competitive intelligence team. (Della Porta (Grail) Tr. 466).

6081. Before transitioning to the Director of Growth Strategy position, Mr. Della Porta served Grail as the Associate Director of Product Marketing. (Della Porta (Grail) Tr. 454).

6082. Mr. Della Porta joined Grail as the Product Marketing Manager in 2016. (Della Porta (Grail) Tr. 454). Mr. Della Porta transitioned to the Senior Manager of Product Marketing role before assuming the role of Associate Director of Product Marketing at Grail. (Della Porta (Grail) Tr. 454).

15. Francis deSouza

6083. Francis deSouza is Illumina's Chief Executive Officer and has been in this role since July 2016. (deSouza (Illumina) Tr. 2190).

6084. As the CEO of Illumina, Mr. deSouza has responsibilities over numerous functions at the company, including strategy, corporate development, finance, legal, and human resources. (deSouza (Illumina) Tr. 2190-91). Mr. deSouza testified at trial that in his role as CEO, his responsibilities include "setting the long-term strategy and vision for the company," "managing the operations of the company to execute against that vision," and that he is the "key point person to manage our relationship with key stakeholders, members of our board, investors, [and] key opinion leaders in the industry." (deSouza (Illumina) Tr. 2306).

6085. Some of Mr. deSouza's direct reports include Susan Tousi, Illumina's Chief Commercial Officer, Dr. Alex Aravanis, Illumina's Chief Technology Officer, Sam Samad, Illumina's Chief Financial Officer, Chuck Dadswell, Illumina's General Counsel, and Joydeep

Goswami, Illumina's SVP of Corporate Development and Strategy. (deSouza (Illumina) Tr. 2191-92).

6086. As Illumina's CEO, Mr. deSouza owes a fiduciary duty to shareholders, including creating long-term value for shareholders and increasing the value of the company. (deSouza (Illumina) Tr. 2193).

6087. [redacted] (deSouza (Illumina) Tr. 2242-43 (*in camera*)).

6088. [redacted] (deSouza (Illumina) Tr. 2243 (*in camera*)).

6089. Mr. deSouza's receives an annual compensation bonus based on meeting certain performance metrics, including certain revenue targets and earnings-per-share targets. (deSouza (Illumina) Tr. 2193-94).

6090. [redacted] (deSouza (Illumina) Tr. 2281 (*in camera*)).

6091. [redacted] (deSouza (Illumina) Tr. 2281 (*in camera*)).

6092. [redacted] (deSouza (Illumina) Tr. 2281 (*in camera*)).

6093. Mr. deSouza joined Illumina in November 2013 as President and member of the Board. (deSouza (Illumina) Tr. 2194, 2308). Mr. deSouza reported to Jay Flatley, Illumina's CEO at the time. (deSouza (Illumina) Tr. 2194). Mr. deSouza is still the president of Illumina, but also assumed the role of CEO in 2016. (deSouza (Illumina) Tr. 2309).

6094. In his role as President at Illumina, Mr. deSouza was primarily responsible for running the "teams that build the products, so it was the product development and engineering teams, the manufacturing teams and quality teams." (deSouza (Illumina) Tr. 2308-09). Mr. deSouza was responsible for the "entire portfolio," which included the range of sequencers, but also included library prep kits, as well as IVDs and software products. (deSouza (Illumina) Tr. 2309).

16. Dr. John Leite

6095. Dr. Leite is the Chief Business Officer of InterVenn and has served in this role since November 2020. (Leite (Illumina) Tr. 2166). In this role, Dr. Leite is responsible for major partnership transactions, corporate strategy and development, as well as commercial activities. (Leite (Illumina) Tr. 2166-67).

6096. Prior to InterVenn, Dr. Leite was employed at Illumina for approximately six and a half years. (Leite (Illumina) Tr. 2073). When he first joined Illumina, Dr. Leite was the Vice President of Clinical Business Development; in this role, he was "responsible for major partnership transactions with either other IVD providers or with pharmaceutical companies across the clinical space." (Leite (Illumina) Tr. 2073). Partnership transactions, in Dr. Leite's testimony, include "transactions that stem outside the normal commercial function and are partnerships, codevelopment agreements, [and] strategic partnerships." (Leite (Illumina) Tr. 2073-74).

6097. When Dr. Leite first joined Illumina, he was responsible for marketing within the Oncology Division, which included the "design of new diagnostic products for what was then a fairly nascent division of Illumina, which was the Oncology Business Unit." (Leite (Illumina) Tr. 2074). In this role, Dr. Leite and the team were "tasked with developing product specifications and product requirements for a whole new generation of diagnostic tests that relied on the Illumina platform," including the TST-170 and TSO-500 oncology selection tests. (Leite (Illumina) Tr. 2074-75).

6098. As part of Dr. Leite's marketing responsibilities early in his employment at Illumina, he was responsible for the TST-170, TSO-500, and a test called Praxis. (Leite (Illumina) Tr. 2076). With respect to the TSO-500, Dr. Leite was responsible for "designing or setting the specifications for the test, securing feedback from physicians who would likely be willing to use our tests, to get a sense for customer requirements, and then to work with the development team to ensure that those requirements were being met, and if any compromises in developments had to be made, how those could be achieved and what impact it would have." (Leite (Illumina) Tr. 2076). Dr. Leite was also responsible for the commercialization strategy. (Leite (Illumina) Tr. 2076).

6099. As part of his work related to the TSO-500, Dr. Leite had to know "pretty much everything" about the test, "including its expected performance, how it differentiates from other similar tests in the market, how it differentiates from the alternative if one were not to use a next-generation sequencing platform, and most importantly, how a physician is likely to make treatment decisions based on the test." (Leite (Illumina) Tr. 2076-77).

6100. Dr. Leite changed positions at Illumina and moved to the Business Development Group, where he had various titles, including Vice President of Strategic Partnerships and Vice President of Clinical Business Development. (Leite (Illumina) Tr. 2079-2080). In his role as Vice President of Clinical Business Development, Dr. Leite's responsibilities "shifted from marketing of the Oncology Division products to the securing of collaborations and partnerships with industry partners, including other IVD companies and pharmaceutical companies." (Leite (Illumina) Tr. 2080).

6101. As part of securing those collaborations and partnerships, Dr. Leite's responsibilities included negotiations collaboration agreements, research activities, co-development agreements, as well as assisting in the development of companion diagnostic tests. (Leite (Illumina) Tr. 2080-81). Moreover, Dr. Leite was responsible for negotiating co-development or collaboration agreements with IVD companies that were focused on the development of in vitro diagnostics that were sold to hospitals and physicians directly.

(Leite (Illumina) Tr. 2081). With these agreements, Illumina provided "access to [Illumina's] IVD sequencing instruments and those companies then validat[ed] their assays on [Illumina's] instruments, as well as securing quality agreements" and "supply agreements that continue to supply them during their development period"; these are commonly referred to as "IVD agreements" at Illumina. (Leite (Illumina) Tr. 2081).

6102. [redacted] (Leite (Illumina) Tr. 2097-98 (*in camera*)).

6103. John Leite was a business development lead for Illumina's PGDx partnership. (PX7093 (Young (Illumina) Dep. at 29)).

6104. Mr. Leite interacted with PGDx on Illumina's PGDx partnership. (PX7093, Young (Illumina) Dep. at 29-30).

6105. Mr. Leite was the lead for Illumina's IVD partnership with Roche. (PX7093, Young (Illumina) Dep. at 26).

6106. When negotiating with oncology therapy selection test developers, Dr. Leite testified at trial that "the ability to maximize penetration into the oncology market was always a consideration. As part of our strategy, we considered the value of inclusion of partners that were developing solutions close to ours. We considered a term called 'cannibalization' – in other words, what would be the sales of Illumina TSO-500 in the absence of these partners versus the presence of these partners – to try and decide at least a framework for summing up what the value of that partnership should be." (Leite (Illumina) Tr. 2084-85).

B. EXPERT WITNESSES WHO TESTIFIED IN TRIAL DEPOSITIONS

1. Dr. Fiona Scott Morton

6107. Dr. Fiona Scott Morton has been a professor at the Yale School of Management for approximately twenty years. (PX7138 (Scott Morton Trial Dep. at 8-10)).

6108. Dr. Scott Morton is a senior consultant with Charles River Associates and has held this position since 2013. (PX7138 (Scott Morton Trial Dep. at 8, 11-12)).

6109. Dr. Scott Morton earned a B.A. in economics from Yale College and a Ph.D. in economics from the Massachusetts Institute of Technology. (PX7138 (Scott Morton Trial Dep. at 9)).

6110. Dr. Scott Morton's primary field of academic research is industrial organization and is an empirical economist that uses data to study firms, markets, and competition. (PX7138 (Scott Morton Trial Dep. at 9)).

6111. Dr. Scott Morton has been a professor at the Stanford Graduate School of Business, University of Chicago Booth School of Business, and Yale School of Management. (PX7138 (Scott Morton Trial Dep. at 9-10)).

6112. Dr. Scott Morton was the chief economist in the Department of Justice Antitrust Division, where she supervised approximately fifty Ph.D. economists on antitrust matters and oversaw "many dozens" of merger matters requiring some analysis. (PX7138 (Scott Morton Trial Dep. at 10-11)).

6113. As a senior consultant with Charles River Associates, Dr. Scott Morton has engaged in matters involving healthcare industries, such as pharmaceuticals, biologics, insurance, as well as some telecommunications and digital work. (PX7138 (Scott Morton Trial Dep. at 12)).

6114. During her time at DOJ and Charles River Associates, Dr. Scott Morton has evaluated mergers that she concluded would not raise competition concerns as well as those that she concluded would raise competition concerns. (PX7138 (Scott Morton Trial Dep. at 12-13)).

6115. Dr. Scott Morton has been accepted as an economic expert witness in previous matters and has testified approximately half a dozen times at trial. (PX7138 (Scott Morton Trial Dep. at 13)).

6116. Dr. Scott Morton belongs to the American Economic Association, as well as the National Bureau of Economic Research. (PX7138 (Scott Morton Trial Dep. at 14)).

2. Dr. Dov Rothman

6117. [redacted] (PX7140 (Rothman Trial Dep. at 7-8); PX6092 (Rothman Rebuttal Report) ¶1 (*in camera*)).

6118. [redacted] (PX7140 (Rothman Trial Dep. at 7); PX6092 (Rothman Rebuttal Report) ¶1 (*in camera*)).

6119. [redacted] (PX6092 (Rothman Rebuttal Report) ¶2 (*in camera*)).

6120. [redacted] (PX6092 (Rothman Rebuttal Report) ¶2 (*in camera*)).

6121. Dr. Rothman has previously served as an expert in other antitrust matters "involving mergers, joint conduct, [and] unilateral conduct." (PX7140 (Rothman Trial Dep. at 9)). As an expert in previous matters, Dr. Rothman "evaluated competitive effects as well as efficiencies." (PX7140 (Rothman Trial Dep. at 9)).

6122. Dr. Rothman has "served as an expert on a number of matters in the healthcare industry, matters involving commercial health insurers, hospitals, physicians, [and] pharmaceuticals." (PX7140 (Rothman Trial Dep. at 9)). Outside of healthcare, Dr.

Rothman has served as an expert in antitrust matters involving the "agriculture, high-tech, [and] consumer electronics" industries. (PX7140 (Rothman Trial Dep. at 9)).

6123. [redacted] (PX7140 (Rothman Trial Dep. at 9-10); PX6092 (Rothman Rebuttal Report) ¶2 (*in camera*)).

6124. Dr. Rothman has previously served as an expert evaluating efficiencies in antitrust matters and testified about efficiencies in three antitrust matters in the chemical and consumer products industries. (PX7140 (Rothman Trial Dep. at 10)).

6125. As an assistant professor at Columbia University, Dr. Rothman taught a course on quantitative research methods as well as a course on healthcare financial management. (PX7140 (Rothman Trial Dep. at 8)). In addition, Dr. Rothman taught at Harvard University, including a course on the economics of merger analysis. (PX7140 (Rothman Trial Dep. at 8-9)).

6126. Dr. Rothman has published work in various journals, including *Antitrust Law Journal*, *Journal of Competition Law & Economics*, *Journal of Health Economics*, among others. (PX7140 (Rothman Trial Dep. at 10-11); *see also* PX6092 (Rothman Rebuttal Report) ¶3 (*in camera*)). In addition, Dr. Rothman serves as a senior editor of the Antitrust Law Journal. (PX7140 (Rothman Trial Dep. at 11)).

6127. In addition to his work as an expert, Dr. Rothman has "worked as a consultant on a range of matters on behalf of the DOJ, the FTC, as well as private parties." (PX7140 (Rothman Trial Dep. at 11)).

3. Dr. Amol Navathe

6128. Dr. Amol Navathe is a faculty member at the University of Pennsylvania School of Medicine and at The Wharton School as well as a staff physician and core investigator at the Philadelphia VA Medical Center. (PX7139 (Navathe Trial Dep. at 7)). Dr Navathe is an affiliate of the Analysis Group, where he does expert witness work in conjunction with the organization. (PX7139 (Navathe Trial Dep. at 13)).

6129. As part of his employment at the University of Pennsylvania School of Medicine and the Wharton School, Dr. Navathe has teaching responsibilities, including teaching courses in healthcare reform, evaluating healthcare programs and policies, as well as a number of clinical responsibilities teaching medical residents and students on the clinical wards. (PX7139 (Navathe Trial Dep. at 7-8)). Dr. Navathe has taught courses that cover material relating to the FDA approval process, the evidentiary requirements for FDA approval, reimbursement by public and private payers. (PX7139 (Navathe Trial Dep. at 8)).

6130. Dr. Navathe's field of academic research is focused on health economics, including "three core domains": (1) "the impact of healthcare programs and policies on patient outcomes, access to care, access to technologies, patient outcomes, healthcare costs, and a number of other outcomes"; (2) working "collaboratively with health systems and health insurance companies, particularly private insurers, to design new interventions that are used to

influence clinical decision-making"; and (3) utilizing "machine learning and predictive analytic techniques to study clinical decision-making" as well as studying new technologies that use these types of machine learning types of algorithms and their impact in clinical decision-making. (PX7139 (Navathe Trial Dep. at 8-9)).

6131. Some of Dr. Navathe's research has related to value-based payment models, which are payments models involving the "final payment amount in reference to the value, in other words, in terms of the patient outcome, the quality, the patient experience or a number of other measures that are intended to assess the quality and the value of the service or product delivered." (PX7139 (Navathe Trial Dep. at 9-10)).

6132. Some of Dr. Navathe's research has related to reimbursement for medical devices by public payers. (PX7139 (Navathe Trial Dep. at 10-11)). Dr. Navathe's research has "examined the implications of the vast amounts of new types of data that have become available to algorithms, including detailed clinical data . . . that's available, for example, in an electronic health record, and the implications for devices that use machine learning algorithms to interpret this data" as well as providing input to clinicians regarding making healthcare decisions that ultimately affect patients. (PX7139 (Navathe Trial Dep. at 11-12).

6133. Dr Navathe's research has considered the type of evidence that the FDA may consider in approving medical diagnostics. (PX7139 (Navathe Trial Dep. at 12).

6134. Dr. Navathe has published over one hundred peer-reviewed articles, including articles published in Science, "which is widely considered to be the top science journal," the New England Journal of Medicine, the Journal of the American Medical Association, the British Medical Journal, the Annals of Internal Medicine, as well as Health Affairs, "which is the top health policy journal." (PX7139 (Navathe Trial Dep. at 12-13)).

6135. Dr. Navathe is the cofounder of a healthcare technology company called Embedded Healthcare, which uses insights from behavioral science and behavioral economics and psychology to design interventions that health insurance companies and health systems can use at the point of care to improve clinical decision-making. (PX7139 (Navathe Trial Dep. at 13)).

6136. Dr. Navathe is a commissioner of the Medicare Payment Advisory Commission (MedPAC) and has served in this role since 2018. (PX7139 (Navathe Trial Dep. at 14)). MedPAC is a nonpartisan agency of the U.S. Congress that works directly with the Senate Finance Committee, the House Ways and Means Committee, and the House Energy and Commerce Committee on all aspects of Medicare policy, providing neutral recommendations from a political perspective based on data analysis and the best available evidence to Congress as well as providing recommendations directly to the CMS. (PX7139 (Navathe Trial Dep. at 14).

6137. Dr. Navathe has consulting experience related to seeking reimbursement for medical products. (PX7139 (Navathe Trial Dep at 15)). Dr. Navathe "worked extensively with manufacturers to help develop market access plans and strategies" to approach payers,

including private payers, "to secure reimbursement" as well as to "structure a variety of different types of value-based or outcome-based or risk-based types of contracts." (PX7139 (Navathe Trial Dep. at 16)).

6138. Dr. Navathe has professional experience working with the FDA. (PX7139 (Navathe Trial Dep. at 16-17). Dr. Navathe was a senior program manager and medical officer at the Department of Health and Human Services in the Office of the Secretary from 2009 to 2011, including leading a $1.1 billion comparative effectiveness research program that was funded through the Recovery Act. (PX7139 (Navathe Trial Dep. at 17)). In that work, Dr. Navathe testified that he "worked extensively with the FDA on the development and direct investment of the federal government in data infrastructure to support comparative effectiveness and to also support real-world evidence research that could be utilized by the FDA." (PX7139 (Navathe Trial Dep. at 17)). Further, Dr. Navathe "worked collaboratively with the FDA on a project called the Mini-Sentinel project" in which HHS worked directly with private payers to set up a multipayer claims database to support the type of post-market surveillance after FDA approval of medical products. (PX7139 (Navathe Trial Dep. at 17)).

6139. Dr Navathe's work at HHS related to the evidentiary requirements for premarket approval from the FDA. (PX7139 (Navathe Trial Dep. at 17-18)).

6140. Dr. Navathe has a bachelor's of science in electrical engineering and economic systems from Stanford University, a medical doctorate degree from the University of Pennsylvania School of Medicine; and a Ph.D. in healthcare management and economics from The Wharton School at the University of Pennsylvania. (PX7139 (Navathe Trial Dep. at 6-7)).

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

1. Brian Blanchett

6141. Mr. Brian Blanchett is a Senior Director of Finance at Illumina and has been in this role since joining the company in July 2019. (PX7067 (Blanchett (Illumina) IHT at 5, 15)).

6142. As the Senior Director of Finance at Illumina, Mr. Blanchett's responsibilities include "assist[-ing] the corporate and business development organization in doing financial analysis" as well as rolling up the consolidated financial results of the company and reporting those to executives. (PX7067 (Blanchett (Illumina) IHT at 19)).

2. David Daly

6143. Mr. David Daly is the President and Chief Operating Officer of Singular Genomics ("Singular"), which he joined in the Spring of 2021. (PX7109 (Daly (Singular Genomics) Dep. at 9, 13)).

6144. As Singular's President and COO, Mr. Daly is responsible for the build-out of the company's commercial organization and overall operations. (PX7109, Daly (Singular Genomics) Dep. at 13)).

6145. Prior to his role as President and COO of Singular Genomics, Mr. Daly was the CEO and board member of Thrive Earlier Detection ("Thrive"). (PX7109, Daly (Singular Genomics) Dep. at 13-14).

6146. Mr. Daly was the CEO of Thrive between August 2019 and January 2021. (PX7109, Daly (Singular Genomics) Dep. at 14).

6147. As Thrive's CEO, Mr. Daly's responsibilities include running the company, interfacing with the development team to see the CancerSEEK test through its various stages of development, and he was "directly involved" with the acquisition process of Thrive by Exact Sciences. (PX7109, Daly (Singular Genomics) Dep. at 14).

6148. Prior to working at Thrive, Mr. Daly was the Senior Vice President and General Manager of the Americas business unit at Illumina. (PX7109, Daly (Singular Genomics) Dep. at 15).

6149. As Illumina's SVP and General Manager of the Americas business unit, Mr. Daly was responsible for overseeing all commercial operations, including sales, marketing, customer service, and field service support. (PX7109, Daly (Singular Genomics) Dep. at 15).

6150. Mr. Daly worked at Illumina between November 2017 and August 2019, and at all times was serving in the role of SVP and General Manager of the Americas business unit. (PX7109 (PX7109, Daly (Singular Genomics) Dep. at 15).

6151. [redacted] (PX7109, Daly (Singular Genomics) Dep. at 107) (*in camera*)).

6152. [redacted] (PX7109, Daly (Singular Genomics) Dep. at 99-100) (*in camera*).

6153. [redacted] (PX7109, Daly (Singular Genomics) Dep. at 101) (*in camera*) (emphasis added)).

3. John Fesko

6154. Mr. John Fesko currently serves as Natera's Chief Business Officer and has been in this role since 2019. (PX7053, Fesko (Natera) IHT at 5-6, 15).

6155. As Chief Business Officer, Mr. Fesko has responsibilities relating to Natera's sales, pricing, and strategic planning. (PX7053, Fesko (Natera) IHT at 16). In addition, Mr. Fesko manages reimbursement, payer contracting, pharma services efforts, and Natera's international business. (PX7053, Fesko (Natera) IHT at 15-16). Furthermore, Mr. Fesko oversees Natera's "partnerships, several of which are focused on research developments, and the acquisition of new technologies, either, you know, outright or through licensing, or partnership also involves research and development. So I work closely with the R&D group at Natera." (PX7053, Fesko (Natera) IHT at 15-16).

6156. Mr. Fesko joined Natera at the beginning of 2014 as Director of Business Development. (PX7053, Fesko (Natera) IHT at 14-15).

6157. As Natera's Director of Business Development, Mr. Fesko "was responsible for most aspects of the company's partnering with third parties." Mr. Fesko would "set up partnerships, evaluate partnerships, [and] negotiate partnerships across the organization." (PX7053, Fesko (Natera) IHT at 15).

6158. Immediately prior to Natera, Mr. Fesko worked for Roche as the Director of Business Development. (PX7053, Fesko (Natera) IHT at 12).

6159. At Roche, Mr. Fesko was responsible for technology evaluation, strategy, and partnership deals with pharmaceutical companies working specifically with molecular diagnostic groups. (PX7053, Fesko (Natera) IHT at 13).

6160. Prior to working at Roche, Mr. Fesko held positions at Novartis, NPM Capital, and an oncology diagnostics company called Invivoscribe. (PX7053, Fesko (Natera) IHT at 12).

6161. At Invivoscribe, Mr. Fesko worked on partnerships, sales, ran diagnostic tests within their lab, conducted research, and manufactured oncology kits. (PX7053, Fesko (Natera) IHT at 13).

6162. Mr. Fesko studied biochemistry during his undergraduate degree and has an M.B.A. (PX7053, Fesko (Natera) IHT at 11-12).

4. Neil Gunn

6163. Mr. Neil Gunn was the President of Roche Sequencing Solutions from January 2016 to March 2021. (PX7043, Gunn (Roche) IHT at 4, 21-22).

6164. In January 2016, Mr. Gunn became the President of Roche Sequencing. In this role, Mr. Gunn "was responsible for all of the activities from research [] to the commercialization of the products. That would include the quality programs, the regulatory programs, the clinical activities. The products were manufactured by a different part of Roche, and the products were sold by a different part of Roche, so operations and commercial sales activities was not [Mr. Gunn's] responsibility." (PX7043, Gunn (Roche) IHT at 22).

6165. Mr. Gunn joined Roche Molecular Systems in October 2008 as Head of Business for Roche Molecular Diagnostics. (PX7043, Gunn (Roche) IHT at 18).

6166. In September 2015, Mr. Gunn transitioned out of the Head of Business for Roche Molecular Diagnostics and into the role of Chief Commercial Officer for Roche Sequencing. (PX7043, Gunn (Roche) IHT at 21).

6167. As Chief Commercial Officer, Mr. Gunn was "responsible for the lifecycle teams, for the development, [and] the clinical programs." (PX7043, Gunn (Roche) IHT at 21).

6168. Prior to joining Roche, Mr. Gunn worked at Pall Corporation in a "scientific marketing role and then rose to the position of marketing director[.]" (PX7043, Gunn (Roche) IHT at 13-14).

6169. Mr. Gunn's specialty role in filtration at Pall Corporation had applications in the clinical oncology space as "the transfusion of blood is a very frequent process in oncology patients, particularly in leukemias, but in all oncology, transfusion of blood is not an unusual practice." (PX7043, Gunn (Roche) IHT at 14-15).

6170. Mr. Gunn worked at Pall Corporation for 14 years before relocating to San Francisco, California to become the senior director of global marketing for Chiron. (PX7043 (Gunn (Roche) IHT at 15)).

6171. Mr. Gunn has an undergraduate degree in biology, a master's degree in science, and a Ph.D. in microbiology from the University of Portsmouth. (PX7043, Gunn (Roche) IHT at 13).

5. Dr. Nicholas Naclerio

6172. Dr. Nicholas Naclerio is a founding and managing partner of Illumina Ventures, which he joined in 2016. (PX7060, Naclerio (Illumina) IHT at 13-14)).

6173. Dr. Naclerio joined Illumina in 2010 by assisting the company in "set[-ting] up a corporate venture fund for them" and then "took on a number of other responsibilities in corporate development [and] corporate strategy." (PX7060, Naclerio (Illumina) IHT at 15)). Dr. Naclerio was the general manager of Illumina's enterprise informatics business unit. (PX7060, Naclerio (Illumina) IHT at 15)). He left Illumina to join Illumina Ventures in 2016. (PX7060, Naclerio (Illumina) IHT at 15-16)).

6174. When Dr. Naclerio first joined Illumina, his title was Senior Vice President of Corporate and Venture Development. (PX7060, Naclerio (Illumina) IHT at 16)). In this role, Dr. Naclerio managed between a "dozen and two dozen people over time," with one part of the team managing "Illumina's strategic planning process," another part of the team handling "routine business development" such as in-licensing, out-licensing, and supply agreements, and another part of the team was "work[-ing] on venture investments and other corporate transactions." (PX7060, Naclerio (Illumina) IHT at 16)).

6175. Dr. Naclerio was a "primary person" involved in Illumina's mergers and acquisitions activities, indicating that he and his team "would be the ones to work with lawyers, bankers, accountants" to "effect the transaction, to negotiate the merger agreements," and ensure that due diligence was properly done. (PX7060, Naclerio (Illumina) IHT at 17)).

6176. Dr. Naclerio "worked with people in R&D and marketing and other parts of the company to put together the strategic planning, you know, strategic plan documents, which would include competitive analysis, so in that regard, we were I would say part of the process of competitive analysis." (PX7060, Naclerio (Illumina) IHT at 19)).

6177. Dr. Naclerio was involved in Illumina's decision to start Grail, including being involved in "general discussions" as well as "involved in the more specific tactical implementation" of the transaction. (PX7060, Naclerio (Illumina) IHT at 23-24)).

6178. As a "member of the senior management team," Dr. Naclerio was involved in the decision to spin Grail out of Illumina. (PX7060, Naclerio (Illumina) IHT at 28)).

6. Cynthia Perettie

6179. Ms. Cynthia Perettie joined FMI as CEO in 2019 when Roche purchased FMI. (PX7068, Perettie (FMI) IHT at 14, 17-18).

6180. As CEO of FMI, Ms. Perettie "over[saw] all of the operations within the company. And that includes everything from research through commercialization and anything in between. So all aspects of quality, regulatory, all of that." (PX7068, Perettie (FMI) IHT at 14-15).

6181. Ms. Perettie joined Roche in May 2017 as Senior Vice President of Global Product Strategy of Oncology and served in that role for two years. (PX7068, Perettie (FMI) IHT at 14).

6182. As Senior Vice President, Ms. Perettie was responsible for "overseeing the oncology pipeline for Roche [and] all of the associated tasks, from drug development through commercialization for those products around the globe." (PX7068, Perettie (FMI) IHT at 14).

6183. Immediately prior to joining Roche, Ms. Perettie worked at Genentech as a "project team leader and life cycle leader for Avastin," before becoming the head of Genentech's breast cancer franchise in the U.S. sales and marketing operation; she then would become Genentech's head of oncology globally. (PX7068, Perettie (FMI) IHT at 13).

6184. At Chiron, Ms. Perettie "did research on antisense, the small genes, small DNA and RNA fragments targeting KDR inflict." (PX7068, Perettie (FMI) IHT at 12).

6185. After leaving Johns Hopkins, Ms. Perettie worked in the research department at Chiron Corporation before moving over to their marketing team. (PX7068, Perettie (FMI) IHT at 12).

6186. Ms. Perettie worked at Johns Hopkins University as a research assistant. (PX7068 (Perettie (FMI-Roche) IHT at 11)). As a research assistant, Ms. Perettie was tasked with the "creation of small fragments of DNA that were used as potential therapeutics in ocular and oncology disorders." (PX7068, Perettie (FMI) IHT at 11).

6187. Ms. Perettie has a bachelor's degree in biochemistry from the State University of New York at Potsdam and an MBA from St. Mary's College of California. (PX7068, Perettie (FMI) IHT at 10-11).

7. Dr. Bert Vogelstein

6188. Dr. Bert 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).

6189. 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)).

6190. Dr. Vogelstein previously served as an Assistant Professor of Oncology at Johns Hopkins University. (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 1)).

6191. Dr. Vogelstein submitted a declaration to the FTC dated March 24, 2021. (*See* PX8400 (Vogelstein (Johns Hopkins University) Decl.)).

6192. 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).

6193. 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).

6194. 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).

6195. 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).

6196. 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).

6197. Dr. Vogelstein testified in his deposition 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. 61).

6198. Dr. Vogelstein is a co-founder of Thrive Earlier Detection Corp. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 27).

6199. Thrive was formed after it acquired a company Dr. Bert Vogelstein co-founded named PapGene. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 28).

6200. 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).

6201. 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).

6202. Dr. Vogelstein testified that his lab has "published so much on liquid biopsies that [they] receive requests from numerous [NGS] companies weekly to try to sell [them] instruments that could be used for liquid biopsies." (PX7101, Vogelstein (Johns Hopkins University) Dep. at 78-79).

6203. Dr. Vogelstein testified that "it's to [NGS manufacturer] companies' benefit to contact [them] whenever they have an instrument that they think would be of interest to" Dr. Vogelstein's lab and his lab "would definitely be interested in evaluating such instruments if they met the several criteria" they will need for their research. (PX7101, Vogelstein (Johns Hopkins University) Dep. at 79).

6204. Dr. Vogelstein completed a post-doctorate fellowship at the National Cancer Institute, where he focused on new technologies in molecular biology. (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 1).

6205. Dr. Vogelstein received his undergraduate degree from the University of Pennsylvania, where he graduated *summa cum laude* with distinction in mathematics, and his medical degree from Johns Hopkins University of Medicine. (PX8400 (Vogelstein (Johns Hopkins University) Decl. ¶ 1).

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

6206. On the first page of their Pretrial Brief, Respondents claim that "GRAIL has developed an early screening test, Galleri, that can simultaneously screen for more than 50 cancers in asymptomatic patients who have no signs of cancer." (*See* Respondents' Pretrial Brief at 1, Aug. 18, 2021) (Respondents provide no citation for this claim)).

6207. Galleri has not been clinically shown to be able to detect more than 50 cancers in an asymptomatic population. (*See infra* Section X.B.2 (Grail's CCGA Study Involved Participants Who Had Already Been Diagnosed with Cancer) and Section X.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)).

6208. Galleri has not been clinically shown to be able to provide "early detection" of more than 50 cancers – even when assessed in a non-screening setting including symptomatic cancer patients. (*See infra* Section X.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)).

6209. {[redacted]}

A. DEFINITIONS & BACKGROUND

1. Cancer Staging

6210. "Stage describes the extent or spread of cancer at the time of diagnosis." (RX3030 at 011 (American Cancer Society, Cancer Facts and Figures 2019)).

6211. Cancer is considered to be localized in Stages I-II. (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) (defining "localized" cancers as "stage I-II").

6212. Cancer is local if it is "confined entirely to the organ or origin." (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019)).

6213. By Stage IV, cancer is considered to be distant. (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) (defining the stages "before distant metastases" as "stage[s] I-III").

6214. Cancer is distant if it "has spread to parts of the body remote from the primary tumor either by direct extension or by discontinuous metastasis to distant organs, tissues, or via the lymphatic system to distant lymph nodes." (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019)).

6215. Stage IV cancer is not early-stage cancer. (Ofman (Grail) Tr. 3430).

6216. "While Stage IV cancer may be treated (resulting in prolongation of life), it is almost always incurable and will eventually result in the death of the patient." (RX3869 (Cote Rebuttal Report) ¶ 31).

6217. Late-stage cancers are generally easier to detect than early-stage cancers. (Bishop (Grail) Tr. 1429-1430).

6218. A November 2019 Grail Board of Directors presentation identified {[redacted]} (PX4172 (Grail) at 050 (Grail, Board of Directors Presentation, Nov. 21, 2019) (*in camera*)).

6219. In June 2021, Grail publicly described "clinical stages I-III" as "early [cancer] stages." (RX3041 at 006 (Interim Results of Pathfinder, June 4, 2021)).

2. Early Detection

6220. {[redacted]} (Rabinowitz (Natera) Tr. 353-4 (*in camera*)).

6221. Early detection of cancer means detecting cancer at earlier stages. (Ofman (Grail) Tr. 3430).

6222. One of the most important attributes of a screening test is the ability to detect cancers at relatively early stages. (Conroy (Exact) Tr. 1701; *see also* PX4178 (Grail) at 009, Nephron Healthcare Investment Research, "Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020 ("The goal of screening is to find cancers early, before they metastasize and become a bigger problem.").

6223. Detecting Stage IV cancer is not an instance of early cancer detection. (Ofman (Grail) Tr. 3431).

3. MCED Tests Are Screening Tests to Detect Cancer in Asymptomatic Populations

6224. "Screening actually implies an asymptomatic person." (Abrams, Tr. 3620).

6225. [redacted]

6226. During trial, Respondents' counsel referred to Galleri as a "multicancer screening test for asymptomatic patients":

> Q. Okay. So besides the Galleri test, Mr. Conroy, no other multicancer test is yet on the market. True?
>
> A. What do you mean by "multicancer test"?
>
> Q. No other multicancer screening test for asymptomatic patients is on the market, right?

(Conroy (Exact) Tr. 1709).

4. Background on Grail's Clinical Study Publications

6227. Grail had released results from two clinical studies as of trial: the Circulating Cell-free Genome Atlas ("CCGA") study and the PATHFINDER study. (Aravanis (Illumina) Tr. 1891-92; Cote, Tr. 3993).

6228. The CCGA study comprises three substudies: CCGA-1, CCGA-2, and CCGA-3. (PX7069 (Bishop (Grail) IHT at 79)).

6229. Grail used CCGA-1 and CCGA-2 to develop Galleri. (PX7069 (Bishop (Grail) IHT at 79-80); *see* PX6049 (Grail) at 015-16 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*) ({[redacted]})).

6230. The authors of the CCGA-3 substudy stated that the CCGA-2 substudy was used to "refine[]" Grail's assay and to "develop[]" machine learning classifiers, whereas the CCGA-3 substudy "is a large clinical validation study of [the Galleri] MCED test." (RX3409 at 002 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6231. {[redacted]} (PX6049 (Grail) at 014 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

6232. CCGA-3 used the current version of Galleri, which Grail subsequently launched as an LDT in 2021. (PX7092 (Ofman (Grail) Dep. at 252); PX6049 (Grail) at 016 (Grail, Narrative Response to Second Request, Mar. 1, 2021) (*in camera*)).

6233. Grail published selected results from its CCGA-2 substudy in 2020. (RX3430 at 001 (M.C. Liu at al., *Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA*, Annals of Oncology (2020)).

6234. Grail published selected results from its CCGA-3 substudy in 2021. (RX3409 at 001 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6235. Grail published selected results from its PATHFINDER substudy in 2021. (RX3041 at 001 (Interim Results of Pathfinder, June 4, 2021)).

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

1. Galleri Is Intended for Use as a Screening Test in Asymptomatic Populations

6236. [redacted] (Conroy (Exact) Tr. 1562 (*in camera*)).

6237. Galleri is intended for use as a screening test in asymptomatic populations. (Ofman (Grail) Tr. 3431).

2. Grail's CCGA Study Involved Participants Who Had Already Been Diagnosed with Cancer

6238. Grail's Circulating Cell-free Genome Atlas ("CCGA") study assessed Galleri's ability to detect cancer signals in individuals who already had been diagnosed with cancer. (Cote, Tr. 3994; Ofman (Grail) Tr. 3435).

6239. Dr. Ofman testified that CCGA is "what we call a case-control study, so the cases are newly diagnosed cancer patients." (Ofman (Grail) Tr. 3294-95; *see also* Cote, Tr. 3993).

6240. "Participants eligible for the cancer arm [of the CCGA study] included individuals diagnosed with cancer and/or who were scheduled to undergo biopsy and/or surgical resection for known or highly suspected malignancy." (RX3409 at 002 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6241. The CCGA study included symptomatic cancer participants. (RX3430 at 010 (M.C. Liu at al., *Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA*, Annals of Oncology (2020)); RX3409 at 006 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6242. Dr. Claire Fiala and Eleftherios Diamandis, two researchers affiliated with Mount Sinai Hospital in Toronto, observed in a comment published in the Annals of Oncology (the same journal used by Grail) that the CCGA study compares healthy patients against patients who have already been diagnosed with cancer: "Consequently, the true sensitivity [of Galleri] will likely be significantly lower when used as a screening tool." (PX4178 (Grail) at 024,

(Email from S. Alag, Grail, to A. Chen, Grail, attaching "Nephron Healthcare Investment Research, Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020)).

6243. Nephron Healthcare Investment Research explained that Grail's "CCGA Study Design Compares Enriched Cohort vs a Healthy Control," a feature that "increases the relative sensitivity since individuals with known cancer are enriched." (PX4178 (Grail) at 025, Email from S. Alag, Grail, to A. Chen, Grail, attaching "Nephron Healthcare Investment Research, Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020)) (further stating that Nephron "expect[s] there will be a sensitivity drop off in PATHFINDER" for Galleri relative to Grail's reported CCGA results).

a) Most Cancers in the CCGA Study Were Previously Identified by "Clinical Presentation"

6244. The majority of participants with cancer in the CCGA-3 substudy were identified by clinical presentation: 72.1 percent of cancers were "identified by clinical presentation," whereas 27.9 percent of cancers were "identified by [other] screening test[s]." (RX3409 at 006 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6245. The majority of participants with cancer in the CCGA-2 substudy were also identified by clinical presentation: 76 percent of cancers were diagnosed by "clinical presentation" whereas 24 percent of cancers were diagnosed by "screening." (RX3773 at 025, Table S1 ("Participant demographics and baseline characteristics") (Liu et al., Supplementary Information to Klein et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set (2021) (*see* notes to Table S1 stating that the data presented "[r]epresents second CCGA sub-study and STRIVE study . . . primary analysis populations").

b) Galleri Performed Substantially Worse at Detecting Cancers Identified by Other Screening Tests in the CCGA-3 Substudy Than at Identifying Cancers Previously Identified by "Clinical Presentation"

6246. The authors of the CCGA-3 substudy noted that "overall sensitivity in cancers identified by clinical presentation [63.9% (61.8% - 66.0%)] was higher than that in cancers identified by screening tests [18.0% (15.5% - 20.8%)]." (RX3409 at 005 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

3. CCGA Included Stage IV Cancer Cases

6247. The cancer arm of the CCGA study included individuals diagnosed with Stage IV cancer. (Cote, Tr. 3994; RX3409 at 006, Table 1 (E. A. Klein et al., *Clinical Validation of a*

Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021))).

a) 21.9% of the Cancer Cases in CCGA-3 Were Stage IV Cancers

6248. Over 600 of the 2,823 participants in the cancer arm of the CCGA-3 substudy had been previously diagnosed with Stage IV cancer. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6249. Individuals with previously diagnosed Stage IV cancer accounted for 21.9% of the individuals in the cancer arm of the CCGA-3 substudy. (RX3409 at 006, Table 1 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6250. Individuals with previously diagnosed Stage IV cancer accounted for between 23% and 24% of the individuals in the cancer arm of the CCGA-2 substudy. (RX3773 at 025, Table S1 ("Participant demographics and baseline characteristics") (Liu et al., Supplementary Information to Klein et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set (2021).

b) 38.3% of the Cancer Cases for Which Galleri Detected a Signal in CCGA-3 Were Stage IV Cancers

6251. Over 550 of the 1,453 participants in the CCGA-3 substudy for which Galleri detected a cancer signal had been previously diagnosed with Stage IV cancer. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6252. Individuals with previously diagnosed Stave IV cancer accounted for 38.3% of the true positive results returned by the Galleri test in the CCGA-3 substudy. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021)) (557 / 1453 = 38.3%)).

c) Galleri Performed Substantially Worse at Detecting Earlier Stage Cancers in the CCGA-3 Substudy Than at Identifying Stage IV Cancers

6253. The authors of the CCGA-3 substudy reported that Galleri's "overall sensitivity across cancer classes and stages was 51.5%." (RX3409 at 005 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6254. The Galleri test detected a cancer signal for 90.1% of individuals with Stage IV cancer in the CCGA-3 substudy. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6255. For participants in the CCGA-3 substudy with previously diagnosed Stage I-III cancers, however, the sensitivity of the Galleri test was 40.7%. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6256. The Galleri test failed to detect a cancer signal for 59.3% of individuals previously diagnosed with Stage I-III cancers in the CCGA-3 substudy. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6257. For participants in the CCGA-3 substudy with previously diagnosed Stage I-II cancers, the sensitivity of the Galleri test was 27.5%. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

6258. The Galleri test failed to detect a cancer signal for 72.5% of individuals previously diagnosed with Stage I-II cancers in the CCGA-3 substudy. (RX3409 at 009, Table 2 (E. A. Klein et al., *Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set*, Annals of Oncology (2021))).

4. Grail's CCGA Study Did Not Involve the Intended Use Population for Galleri (Asymptomatic Screening Population)

6259. Dr. Ofman testified that the CCGA study did not involve the intended use population for Galleri. (Ofman (Grail) Tr. 3294-95).

6260. Dr. Ofman testified that Grail undertook the SUMMIT and STRIVE studies because, after the CCGA study, "we needed to also study our assay in what we call the intended use population." (Ofman (Grail) Tr. 3294-95).

6261. As of trial, Grail had not analyzed the data from either the SUMMIT or STRIVE studies. (Ofman (Grail) Tr. 3294-95 ("[W]e haven't analyzed those data yet because we're reserving them for our FDA submission on the next version of our test.")).

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

6262. [redacted] (PX4609 (Grail) at 016 (*in camera*)).

6263. Results from early studies or trials are not necessarily predictive of future clinical trial results. (Conroy (Exact) Tr. 1712).

6264. Mr. Conroy, CEO and Chairman of Exact, testified about the limitations of a case control study versus a "true screening setting," in response to questions from Mr. Marriott:

Q. And the Cohen study, it had several limitations. Is that fair to say?

A. I think that is fair to say.

Q. And, in fact, they're acknowledged by the authors, that the patient cohort in the study was comprised of individuals with known cancers, most diagnosed on the basis of symptoms of disease. Fair to say?

A. Yes. That's a limitation.

Q. Okay. And moreover, most individuals in a true screening setting would have less advanced disease, right?

A. Yes.

Q. And another limitation here was that the study's controls were limited to healthy individuals, right?

A. Well, that's what this says. You know, I'm not an expert on the actual study.

Q. Okay. Buy you understand that a true cancer screening – that in a true cancer screening setting, some individuals might have inflammatory or other diseases which could result in a greater proportion of false-positive results than observed in the study, right?

A. I – I agree with that statement, yes.

. . .

Q. And the proportion of cancers of each type in the cohort was not representative of those in the United States as a whole. Fair to say?

A. That's usually the case with case-control studies, and it appears to be the case here.

(Conroy (Exact) Tr. 1701-02 (discussing RX3142 (Joshua Cohen, et al., Detection and Localization of Surgically Resectable Cancers with a Multi-Analyte Blood Test, 359 Science 926 (2018)); *see* PX7058 (Conroy (Exact) IHT at 106-107) (*in camera*) ([redacted])).

6265. The authors of Grail's CCGA-2 substudy acknowledge that CCGA does not enable an understanding of how Galleri would perform in an asymptomatic screening population: "[T]he [CCGA] study has limitations. Participants with cancer were not all asymptomatic; to understand performance in an asymptomatic screening population will require additional

studies, which are ongoing." (RX3430 at 10 (M.C. Liu, et al., Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 6 Annals of Oncology 745 (2020))).

6266. The authors of Grail's CCGA-3 substudy identify as a "limitation" of CCGA "that CCGA is a case-control study, and as such, is not reflective of performance in a screening population." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021))).

6267. The authors of Grail's CCGA-3 substudy further identify as a "limitation" of CCGA "that the blood samples collected from participants with cancer after biopsies had been carried out could increase the possibility that the tumor cfDNA fraction may increase relative to before the biopsy." (RX3409 at 010 (E.A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, 9 Annals of Oncology 1167 (2021))).

6268. The Galleri CCGA study excluded individuals with "[p]oor health status" or "[a]cute exacerbation or flare of an inflammatory condition requiring escalation in medical therapy within 14 days prior to blood draw." (RX3773 at 032 , Table S1 ("Participant Inclusion and Exclusion Criteria") (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

6269. [redacted]} (Conroy (Exact) Tr. 1571 (*in camera*)).

6270. [redacted]} (Lengauer (Third Rock Ventures) Tr. 192-93 (*in camera*)).

6271. [redacted]} (PX4609 (Grail) at 021 [redacted] (*in camera*); *see also* Ofman (Grail) Tr. 3407-08 (*in camera*)).

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

6272. At trial, Grail Chief Medical Officer, Dr. Josh Ofman, defined "clinical validation" as "does the test perform as predicted in the intended use population, a population that the test will actually be used in." (Ofman (Grail) Tr. 3284-85).

6273. Dr. Gary Gao, co-founder of Singlera, testified that "the evidence from a case-control study cannot be expansive to a[n] asymptomatic population for early cancer screening." (Gao (Singlera) Tr. 2933-34).

6274. Dr. Gao testified that the FDA "usually require[s] a randomized clinical trial, [what] we call a pivotal – prospective pivotal trial. So that means you follow a healthy population with no symptoms from today, while you start your trial over hundreds of sites." (Gao (Singlera) Tr. 2886-87).

6275. Dr. Ofman testified that "there should be robust analytical and clinical validation at population scale to support [an MCED] test's deployment in the population." (Ofman (Grail) Tr. 3291).

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

6276. The fifty-plus cancers that Grail claims Galleri can detect are listed on RX2770, which is a poster presented at the American Society of Clinical Oncology ("ASCO") in June 2021, based on the CCGA study. (Bishop (Grail) Tr. 1374-75; RX2770 at 001 (2021 ASCO CCGA Poster)).

6277. The ASCO Poster for CCGA claims that Galleri can provide "Detection of a Cancer Signal for over 50 AJCC Cancer Types." (RX2770 at 001 (2021 ASCO CCGA Poster)).

6278. Grail uses definitions from the American Joint Committee on Cancer ("AJCC") to identify cancer types. (RX2770 at 001 (2021 ASCO CCGA Poster)).

6279. For instance, Grail breaks down colon and rectum cancer into multiple different AAJC cancer types for counting purposes. (Ofman (Grail) Tr. 3433).

6280. Dr. Cote testified that AJCC types are the standard way that clinicians would "subclassify" cancer. (Cote Tr. 3796).

6281. The CCGA poster presented at ASCO in June 2021 lists 51 AJCC cancer types as having been "detected" by Galleri (excluding repeated entries):

1) Anus
2) Urinary bladder
3) Breast
4) Cervix uteri
5) Appendix carcinoma
6) Colon and rectum
7) Neuroendocrine tumors of the appendix
8) Neuroendocrine tumors of the colon and rectum
9) Esophagus and esophagogastric junction
10) Distal bile duct
11) Gallbladder

12) Perihilar ducts
13) HPV-mediated (p16+) oropharyngeal cancer
14) Larynx
15) Nasal cavity and paranasal sinuses
16) Nasopharynx
17) Oral cavity
18) Oropharynx (p16-) and hypopharynx
19) Kidney
20) Intrahepatic bile ducts
21) Liver
22) Lung
23) Hodgkin and non-Hodgkin lymphoma
24) Melanoma of the skin
25) Leukemia
26) Ovary, fallopian tube and primary peritoneal carcinoma
27) Exocrine pancreas
28) Neuroendocrine tumors of the pancreas
29) Plasma cell myeloma and plasma cell disorders
30) Prostate
31) Bone
32) Corpus uteri sarcoma
33) Gastrointestinal stromal tumor
34) Soft tissue sarcoma of the abdomen and thoracic visceral organs
35) Soft tissue sarcoma of the head and neck
36) Soft tissue sarcoma of the retroperitoneum
37) Soft tissue sarcoma of the trunk and extremities
38) Soft tissue sarcoma unusual histologies and sites
39) Stomach
40) Renal pelvis and ureter
41) Corpus uteri carcinoma and carcinosarcoma
42) Adrenal cortical carcinoma
43) Ampulla of vater
44) Gestational trophoblastic neoplasms
45) Malignant pleural mesothelioma
46) Merkel cell carcinoma
47) Penis
48) Small intestine
49) Testis
50) Vagina
51) Vulva

(RX2770 at 001 (Habte Ylmer, et al., Detection of Cancer Signal for Over 50 AJCC Cancer Types with a Multi-Cancer Early Detection Test, 2021)).

6282. The CCGA poster presented at ASCO in June 2021 lists the "results" from Grail's "third CCGA substudy" as the basis for the data and claims on the poster. (RX2770 at 001 (2021 ASCO CCGA Poster) (*see* "Conclusions" box of poster)).

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

6283. Dr. Ofman explained that Grail's PATHFINDER study is "an interventional study, which is what we call a real-world clinical practice study," of 6,600 patients from the screening eligible population with no suspicion of cancer. (Ofman (Grail) Tr. 3293).

6284. According to Dr. Ofman, Grail felt that PATHFINDER, "which was an actual return of results study, interventional, in actual clinical practice, would be a more powerful way to add to our clinical validation than [STRIVE and SUMMIT]." (Ofman (Grail) Tr. 3296).

6285. As part of PATHFINDER, patients received results from their test and were tracked for one year. (Ofman (Grail) Tr. 3293, 3296).

6286. Grail publicly reported the interim results from its PATHFINDER study. (Ofman (Grail) Tr. 3293).

6287. At trial, Dr. Ofman summarized the interim results from PATHFINDER, including that Galleri detected 13 cancer types, not 50: "In the PATHFINDER study, [Grail] found 29 cancers, 13 different types of cancer, and some in their early stages." (Ofman (Grail) Tr. 3297-98).

6288. Based on the PATHFINDER study, the Galleri test has been shown to detect seven types of Stage I-III cancer in an asymptomatic screening population. (Cote Tr. 4000-01; RX3041 at 005 (Thomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, 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)).

6289. The PATHFINDER study 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; Ofman (Grail) Tr. 3298).

6290. According to Dr. Ofman, Grail was not concerned that PATHFINDER didn't find 50 cancer types, because to do so "in a real-world population is going to require hundreds of thousands of people, so PATHFINDER was not designed to do that." (Ofman (Grail) Tr. 3298).

6291. [redacted] (Ofman (Grail) Tr. 3323-24 (*in camera*)).

6292. Seventy percent of positive Galleri results were falsely positive for asymptomatic normal-risk participants in PATHFINDER, according to the interim results reported by Grail. (RX3041 at 004 (Thomasz Beer, Interim Results of Pathfinder, a Clinical Use Study Using a Methylation-Based Multi-Cancer Early Detection Test, June 4, 2021) (Fraction calculated based on all participants "without additional risk" for whom Grail reported

diagnostic resolution. Galleri generated 9 true positives and 21 false positives for participants "without additional risk." An additional 6 patients tested positive but are listed as having "no current diagnostic resolution.")).

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

1. Grail's CCGA Study Does Not Provide Clinical Evidence of Galleri's Ability to Detect Cancer Early in a Screening Population

6293. *See* Sections X.B. (Grail's CCGA Study Did Not Assess Galleri's Performance in the Intended Use Population (Asymptomatic Screening Population)) through X.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)).

2. Grail's PATHFINDER Study Provides Clinical Evidence of Galleri's Ability to Detect Only Seven Types of Stage I-III Cancer in an Asymptomatic Population

6294. *See* Complaint Counsel's Proposed Finding of Fact ¶ 6288.

3. Dr. Cote Conceded That Galleri Has Been Clinically Shown to Detect Only Seven Types of Stage I-III Cancer in an Asymptomatic Population

6295. In his report, Dr. Cote wrote that "GRAIL has developed a multicancer screening test, Galleri, that simultaneously screens for over 50 different types of cancer from a single blood sample." (RX3869 (Cote Rebuttal Report) ¶ 133).

6296. Dr. Cote testified that his use of the term "screening" in paragraph 133 of his report "refer[s] to the ability to detect cancers at early stage specifically." (Cote Tr. 3992).

6297. Dr. Cote testified that the only clinical trials of Galleri for which results have been released as of trial were the CCGA study and the PATHFINDER study. (Cote Tr. 3993).

6298. At trial, Dr. Cote conceded that Galleri has been clinically shown to detect only seven types of Stage I through Stage III cancer in an asymptomatic screening population. (Cote Tr. 3994, 4000-01).

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

1. Grail's CCGA-3 Substudy Presents Individual Staging Results for Only 14 of the 51 AJCC Cancer Types Grail Claims Galleri Can Detect

6299. Dr. Ofman testified that the CCGA-3 substudy reported sensitivity by broad cancer classes, but that he could not recall if the CCGA-3 substudy reported sensitivity by cancer stage for each of the individual cancer types for which Grail claims Galleri can detect a signal: "I can't recall if whether the appendix of the CCGA3 paper contained all of that, but certainly we report out, you know, all the cancer classes . . . ." (Ofman (Grail) Tr. 3439).

6300. Dr. Ofman testified that he did not know whether Grail's CCGA-3 substudy counted Galleri as having detected a particular cancer type even if Galleri only detected a cancer signal in subjects with Stage IV cancer. (Ofman (Grail) Tr. 3435-36).

6301. The CCGA-3 substudy reports sensitivity data by clinical cancer stage for cancer classes, not for individual AJCC cancer types. (RX3773 at 038-41, Table S5 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

6302. The CCGA-3 substudy provides individual staging information for the following 14 AJCC cancer types only (the 14 AJCC cancer types that are coterminous with reported "cancer classes"):

AJCC Cancer "Type"	**Coterminous Cancer "Class" (Staging Info Provided)**
Anus	Anus
Urinary bladder	Bladder
Breast	Breast
Cervix uteri	Cervix
Esophagus and esophagogastric junction	Esophagus
Kidney	Kidney
Lung	Lung
Hodgkin and non-Hodgkin lymphoma	Lymphoma
Melanoma of the skin	Melanoma
Ovary, fallopian tube and primary peritoneal carcinoma	Ovary
Plasma cell myeloma and plasma cell disorders	Plasma cell neoplasm
Prostate	Prostate
Renal pelvis and ureter	Urothelial tract
Corpus uteri carcinoma and carcinosarcoma	Uterus

(RX3773 at 038-44, Tables S5 & S6 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

a) <u>Galleri Failed to Identify Any Instances of Early-Stage Melanoma in the CCGA-3 Substudy</u>

6303. Melanoma is one of the AJCC cancer types for which Grail claims Galleri can detect a signal. (Ofman (Grail) Tr. 3436; RX2770 at 001 (2021 ASCO CCGA Poster)).

6304. At trial, Dr. Ofman stated that he did not know whether Galleri detected a cancer signal for any of the CCGA-3 participants with Stage I to Stage III melanoma. (Ofman (Grail) Tr. 3435-37).

6305. Galleri detected a cancer signal for 0 of 7 participants in the CCGA-3 substudy with Stage I-III melanoma. (RX3773 at 039, Table S5 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

6306. The only instances of melanoma that Galleri detected in the CCGA-3 substudy were Stage IV melanoma. (RX3773 at 039, Table S5 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

b) Galleri Failed to Identify Any Instances of Early-Stage Urothelial Tract Cancer in the CCGA-3 Substudy

6307. Urothelial tract cancer is one of the AJCC cancer types for which Grail claims Galleri can detect a signal. (Ofman (Grail) Tr. 3437; RX2770 at 001 (2021 ASCO CCGA Poster)).

6308. Galleri detected a cancer signal for 0 of 2 participants in the CCGA-3 substudy with Stage I-III urothelial tract cancer. (RX3773 at 040, Table S5 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

6309. The only instances of urothelial tract cancer that Galleri detected in the CCGA-3 substudy were Stage IV urothelial tract cancer. (RX3773 at 040, Table S5 (M.C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-Cancer Detection and Localization Using Methylation Signatures in Cell-Free DNA, 2021)).

2. CCGA-3 Does Not Provide Staging Information for 37 of the 51 AJCC Cancer Types that Grail Claims Galleri Can Detect

a) CCGA-3 Provides No Staging Information to Indicate Whether the Single Instance of Cancer Detected for 11 AJCC Cancer Types Was Early-Stage Cancer

6310. Grail claims that Galleri can detect a signal for each of the 11 AJCC cancer types listed in Complaint Counsel's Proposed Findings of Fact ¶ 6311, below. (RX2770 (2021 ASCO CCGA Poster); Bishop (Grail) Tr. 1374-75)).

6311. Galleri identified a single instance of cancer in the CCGA-3 substudy for each of the 11 AJCC cancer types listed below; no staging information about these specific cancer types is provided in the CCGA-3 substudy, supplemental materials published with the CCGA-3 substudy, or the 2021 CCGA ASCO Poster.

AJCC Cancer "Type"	Instances Detected	Stage I-III Instances Detected
Appendix carcinoma	1	Unknown / Not reported
Neuroendocrine tumors of the appendix	1	Unknown / Not reported
Perihilar ducts	1	Unknown / Not reported
Nasal cavity and paranasal sinuses	1	Unknown / Not reported
Adrenal cortical carcinoma	1	Unknown / Not reported
Ampulla of vater	1	Unknown / Not reported
Penis	1	Unknown / Not reported
Bone	1	Unknown / Not reported
Gestational trophoblastic neoplasms	1	Unknown / Not reported
Gastrointestinal stromal tumors	1	Unknown / Not reported
Soft tissue sarcoma of the head and neck	1	Unknown / Not reported

(RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-41 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)); RX2770 at 001 (2021 ASCO CCGA Poster)).

6312. The data presented in the CCGA-3 substudy do not indicate whether the single instance of appendix carcinoma that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038, 042 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of colon/rectum, but not for appendix carcinoma specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6313. The data presented in the CCGA-3 substudy do not indicate whether the single instance of neuroendocrine tumors of the appendix that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038, 042 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of colon/rectum, but not for neuroendocrine tumors of the appendix specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6314. The data presented in the CCGA-3 substudy do not indicate whether the single instance of cancer of the perihilar ducts that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038, 042 (M. C. Liu, et al.,

Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of gallbladder, but not for cancer of the perihilar ducts specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6315. The data presented in the CCGA-3 substudy do not indicate whether the single instance of nasal cavity and paranasal sinus cancer that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-39, 042 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of head and neck, but not for nasal cavity and paranasal sinus cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6316. The data presented in the CCGA-3 substudy do not indicate whether the single instance of adrenal cortical carcinoma that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41, 043 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for adrenal cortical carcinoma specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6317. The data presented in the CCGA-3 substudy do not indicate whether the single instance of ampulla of vater that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41, 043 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for ampulla of vater specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6318. The data presented in the CCGA-3 substudy do not indicate whether the single instance of penile cancer that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41, 043 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for penile cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6319. The data presented in the CCGA-3 substudy do not indicate whether the single instance of bone cancer that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV

cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040, 044 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for bone cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6320. The data presented in the CCGA-3 substudy do not indicate whether the single instance of gestational trophoblastic neoplasms that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41, 043 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for gestational trophoblastic neoplasms specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6321. The data presented in the CCGA-3 substudy do not indicate whether the single instance of gastrointestinal stromal tumors that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040, 044 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for gastrointestinal stromal tumors specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6322. The data presented in the CCGA-3 substudy do not indicate whether the single instance of soft tissue sarcoma of the head and neck that Galleri identified in CCGA-3 was Stage I through III cancer or Stage IV cancer. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038, 044 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for soft tissue sarcoma of the head and neck specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

b) <u>CCGA-3 Provides No Staging Information to Indicate Whether the Five or Fewer Instances of Cancer Detected for a Further 16 AJCC Cancer Types Were Early-Stage Cancers</u>

6323. Grail claims that Galleri can detect a signal for each of the 16 AJCC cancer types listed in Complaint Counsel's Proposed Findings of Fact ¶ 6324, below. (RX2770 at 001 (2021 ASCO CCGA Poster); Bishop (Grail) Tr. 1374-75).

6324. Galleri identified five or fewer instances of cancer in the CCGA-3 substudy for each of the 16 AJCC cancer types listed below; no staging information about these specific cancer types is provided in the CCGA-3 substudy, supplemental materials published with the CCGA-3 substudy, or the 2021 CCGA ASCO Poster.

AJCC Cancer "Type"	Instances Detected	Stage I-III Instances Detected
Neuroendocrine tumors of the colon and rectum	3	Unknown / Not reported
Distal bile duct	3	Unknown / Not reported
Nasopharynx	3	Unknown / Not reported
Oral cavity	3	Unknown / Not reported
Leukemia	2	Cancer Not Staged
Malignant pleural mesothelioma	3	Unknown / Not reported
Merkel cell carcinoma	2	Unknown / Not reported
Small intestine	3	Unknown / Not reported
Testis	5	Unknown / Not reported
Vagina	2	Unknown / Not reported
Vulva	4	Unknown / Not reported
Neuroendocrine tumors of the pancreas	3	Unknown / Not reported
Corpus uteri sarcoma	3	Unknown / Not reported
Soft tissue sarcoma of the abdomen and thoracic visceral organs	2	Unknown / Not reported
Soft tissue sarcoma of the retroperitoneum	2	Unknown / Not reported
Soft tissue sarcoma unusual histologies and sites	2	Unknown / Not reported

(*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-41, Table S5 (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)); RX2770 at 001 (2021 ASCO CCGA Poster)).

6325. The data presented in the CCGA-3 substudy do not indicate whether the three instances of neuroendocrine tumors of the colon and rectum that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038 (Table S5), 042 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of colon/rectum, but not for neuroendocrine tumors of the colon and rectum specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6326. The data presented in the CCGA-3 substudy do not indicate whether the three instances of distal bile duct cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038 (Table S5), 042 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of gallbladder, but not for distal bile duct cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6327. The data presented in the CCGA-3 substudy do not indicate whether the three instances of nasopharyngeal cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-39 (Table S5), 042 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of head and neck, but not for nasopharyngeal cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6328. The data presented in the CCGA-3 substudy do not indicate whether the three instances of oral cavity cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-39 (Table S5), 042 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of head and neck, but not for oral cavity cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6329. The data presented in the CCGA-3 substudy do not indicate whether the two instances of leukemia that Galleri identified in CCGA-3 included any Stage I through III cancers specifically, or "early stage" cancers more generally. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 039, 041 (Table S5), 043 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (the CCGA-3 substudy does not provide staging information for the broader cancer "class" of myeloid neoplasm (with which the cancer type of leukemia is coterminous), stating instead that myeloid neoplasm is "[n]ot expected to be staged."); RX2770 at 001 (2021 ASCO CCGA Poster)).

6330. The data presented in the CCGA-3 substudy do not indicate whether the three instances of malignant pleural mesothelioma that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-

41 (Table S5), 043 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for malignant pleural mesothelioma specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6331. The data presented in the CCGA-3 substudy do not indicate whether the two instances of Merkel cell carcinoma that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for Merkel cell carcinoma specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6332. The data presented in the CCGA-3 substudy do not indicate whether the three instances of small intestine cancer that Grail identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for small intestine cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6333. The data presented in the CCGA-3 substudy do not indicate whether the five instances of testicular cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for testicular cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6334. The data presented in the CCGA-3 substudy do not indicate whether the two instances of vaginal cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043-44 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for vaginal cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6335. The data presented in the CCGA-3 substudy do not indicate whether the four instances of vulvar cancer that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040-41 (Table S5), 043-44 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of "other," but not for vulvar cancer specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6336. The data presented in the CCGA-3 substudy do not indicate whether the three instances of neuroendocrine tumors of the pancreas that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 039-40 (Table S5), 044 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of pancreas, but not for neuroendocrine tumors of the pancreas specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6337. The data presented in the CCGA-3 substudy do not indicate whether the three instances of corpus uteri sarcoma that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040 (Table S5), 044 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for corpus uteri sarcoma specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6338. The data presented in the CCGA-3 substudy do not indicate whether the two instances of soft tissue sarcoma of the abdomen and thoracic visceral organs that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040 (Table S5), 044 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for soft tissue sarcoma of the abdomen and thoracic visceral organs specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6339. The data presented in the CCGA-3 substudy do not indicate whether the two instances of soft tissue sarcoma of the retroperitoneum that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early

Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040 (Table S5), 044 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for soft tissue sarcoma of the retroperitoneum specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

6340. The data presented in the CCGA-3 substudy do not indicate whether the two instances of soft tissue sarcoma with unusual histologies and sites that Galleri identified in CCGA-3 included any Stage I through III cancers, or instead were solely Stage IV cancers. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 040 (Table S5), 044 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021)) (listing staging information for the broader cancer "class" of sarcoma, but not for soft tissue sarcoma with unusual histologies and sites specifically); RX2770 at 001 (2021 ASCO CCGA Poster)).

c) CCGA-3 Provides No Staging Information to Indicate Whether the Six or More Instances of Cancer Detected for a Further 10 AJCC Cancer Types Were Early-Stage Cancers

6341. Grail claims that Galleri can detect a signal for the AJCC cancer types: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (RX2770 at 001 (2021 ASCO CCGA Poster)).

6342. The CCGA-3 substudy provides staging information for the broader cancer "classes" of which the AJCC cancer types are subtypes: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (RX3773 at 038-40 (Table S5), 042-44 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021))).

6343. The CCGA-3 substudy does not provide staging information specifically for AJCC cancer types: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue sarcoma of the trunk and extremities, and stomach. (*See* RX3773 at 038-40 (Table S5), 042-44 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021))).

6344. The data presented in the CCGA-3 substudy do not indicate the number of Stage I through III cancers that Galleri identified in CCGA-3 specifically for AJCC cancer types: colon and rectum, gallbladder, HPV-mediated (p16+) oropharyngeal cancer, larynx, oropharynx (p16-) and hypopharynx, intrahepatic bile ducts, liver, exocrine pancreas, soft tissue

sarcoma of the trunk and extremities, and stomach. (*See* RX3409 (E. A. Klein, et al., Clinical Validation of a Targeted Methylation-Based Multi-Cancer Early Detection Test Using an Independent Validation Set, Annals of Oncology (2021)); RX3773 at 038-40 (Table S5), 042-44 (Table S6) (M. C. Liu, et al., Supplementary Information: Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA (2021))).

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

6345. Grail designed CCGA to determine how many types of cancer Galleri could detect. (Ofman (Grail) Tr. 3298-99).

6346. There was no minimum sensitivity threshold for Grail to report signal detection for particular cancer types in the CCGA-3 substudy. (Ofman (Grail) Tr. 3437-39).

6347. A negative Galleri test "doesn't preclude that there's cancer there." (Ofman (Grail) Tr. 3309-10).

6348. Dr. Ofman testified that, "if you have a negative Galleri test, you still want to encourage the individual to get their single-cancer screening tests." (Ofman (Grail) Tr. 3309-10).

6349. Mr. Bishop testified that doctors make the decision about whether it is appropriate to prescribe Galleri for patients. (Bishop (Grail) Tr. 1375).

6350. [redacted] (Della Porta (Grail) Tr. 531-32 (*in camera*)).

6351. [redacted] (Ofman (Grail) Tr. 3415 (*in camera*); PX4609 (Grail) at 017 [redacted] (*in camera*)).

6352. The Annals of Oncology (the same journal used by Grail) published a comment on CCGA-2 by Dr. Claire Fiala and Eleftherios Diamandis, two researchers affiliated with Mount Sinai Hospital in Toronto, stating: "Initially, the achieved specificity [of Galleri in CCGA-2] looks remarkable . . . [In practice,] the sensitivity for late stage cancers is irrelevant as they are likely detectable by symptoms." (PX4178 (Grail) at 024 (Email from S. Alag, Grail, to A. Chen, Grail, attaching Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly, Nov. 12, 2020)).

6353. A November 2020 investment research report produced by Grail identifies the "relatively low sensitivity of Galleri in early stage cancers" as reported in CCGA-2 as a "[p]otential [i]ssue" for Grail: "The potential value proposition in early cancer detection is just that – in detecting cancers early, where intervention can save lives. As such, the relatively low

sensitivity of Galleri in early stage cancers raises concerns for its ultimate commercial prospects." (PX4178 (Grail) at 019 (Email from S. Alag, Grail, to A. Chen, Grail, attaching Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly, Nov. 12, 2020)).

6354. Nephron Healthcare Investment Research observed that Galleri's "Stage 1 sensitivity for Breast, Esophagus, Kidney, and Prostate Cancer was essentially 0%" in CCGA-2. (PX4178 (Grail) at 020 (Email from S. Alag, Grail, to A. Chen, Grail, attaching Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly, Nov. 12, 2020)).

6355. Galleri's reported sensitivity at detecting Stage 1 and Stage 2 colon/rectum cancer [in CCGA-2] "would not meet CMS' recent proposed NCD criteria of >74% sensitivity and >90% specificity." (PX4178 (Grail) at 020 (Email from S. Alag, Grail, to A. Chen, Grail, attaching Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly, Nov. 12, 2020)).

6356. The CCGA-3 substudy provided data on Galleri's sensitivity at detecting Stage I-III cancers specifically for only 14 of the 51 AJCC cancer types for which Grail claims Galleri can detect a signal. (RX3773 at 038-41, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA)).

1. Melanoma

6357. Melanoma is one of the cancer types for which Grail claims Galleri can detect a signal. (*See* Bishop (Grail) Tr. 1374-75; RX2770 at 001 (2021 ASCO CCGA Poster)).

6358. The CCGA-3 substudy reports Galleri's overall sensitivity in detecting melanoma as 46.2 percent. (Ofman (Grail) Tr. 3436; RX3409 at 007, Figure 3 (Klein, et al., Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set, 2021); RX2770 at 001 (2021 ASCO CCGA Poster)).

6359. Galleri's sensitivity for Stage I-III melanoma in the CCGA-3 substudy was 0.0%. (*See* RX3773 at 039, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (Zero test positives for Stage I-III melanoma out of 7 participants in the substudy with Stage I-III melanoma)).

6360. Galleri failed to detect 100% of early-stage melanoma cases in the CCGA-3 substudy. (Ofman (Grail) Tr. 3430, 3436-37; *see* RX3773 at 039, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (Zero test positives for Stage I-III melanoma out of 7 participants in the substudy with Stage I-III melanoma)).

6361. Melanoma is estimated to be the fifth leading site for new cancer cases for both men and women in the United States. (RX3030 at 012, Figure 3 (American Cancer Society, Cancer Facts & Figures 2019)).

6362. The five-year survival rate for melanoma diagnosed when it is local is 98 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (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) (defining "localized" cancers as "stage I-II")).

6363. The five-year survival rate for melanoma diagnosed when it is distant is 23 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (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) (defining "stage[s] I-III" as the stages "before distant metastases")).

2. Urothelial Tract Cancer

6364. Urothelial tract cancer is one of the cancer types for which Grail claims Galleri can detect a signal. (*See* Bishop (Grail) Tr. 1374-75; RX2770 at 001 (2021 ASCO CCGA Poster)).

6365. The CCGA-3 substudy reports Galleri's sensitivity in detecting urothelial tract cancer as 80.0 percent. (RX3409 at 007, Figure 3 (Klein, et al., Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set, 2021); RX2770 at 001 (2021 ASCO CCGA Poster)).

6366. Galleri's sensitivity for Stage I-III urothelial tract cancer in the CCGA-3 substudy was 0.0%. (*See* RX3773 at 040, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (0 test positives for Stage I-III urothelial tract cancer out of 2 participants in the substudy with Stage I-III urothelial tract cancer)).

6367. Galleri failed to detect 100% of early-stage urothelial tract cancers in the CCGA-3 substudy. (Ofman (Grail) Tr. 3437; *see* RX3773 at 040, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (0 test positives for Stage I-III urothelial tract cancer out of 2 participants in the substudy with Stage I-III urothelial tract cancer)); Ofman (Grail) Tr. 3430).

3. Prostate Cancer

6368. Prostate cancer is one of the cancer types for which Grail claims Galleri can detect a signal. (*See* Bishop (Grail) Tr. 1374-75; RX2770 at 001 (2021 ASCO CCGA Poster)).

6369. The CCGA-3 substudy reports Galleri's sensitivity in detecting prostate cancer as 11.2 percent. (RX3409 at 007, Figure 3 (Klein, et al., Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set, 2021); RX2770 at 001 (2021 ASCO CCGA Poster)).

6370. Galleri detected a cancer signal for 22 of 388 participants in the CCGA-3 substudy with Stage I-III prostate cancer. (RX3773 at 040, Table S5 (Liu, et al., Sensitive and Specific

Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA)).

6371. Galleri's sensitivity for Stage I-III prostate cancer in the CCGA-3 substudy was 5.7%. (*See* RX3773 at 040, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (22 test positives for Stage I-III prostate cancer out of 388 participants in the substudy with Stage I-III prostate cancer)).

6372. Galleri failed to detect over 94% of instances of early-stage prostate cancer in the CCGA-3 substudy. (Ofman (Grail) Tr. 3438; *see* RX3773 at 040, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (22 test positives for Stage I-III prostate cancer out of 388 participants in the substudy with Stage I-III prostate cancer)).

6373. Prostate cancer is estimated to be the number one site of new cancer cases for men in the United States. (RX3030 at 012, Figure 3 (American Cancer Society, Cancer Facts & Figures 2019).

6374. Prostate cancer is estimated to be the second leading cause of estimated cancer deaths for men in the United States. (RX3030 at 012, Figure 3 (American Cancer Society, Cancer Facts & Figures 2019).

6375. The five-year survival rate for prostate cancer diagnosed when it is local is greater than 99 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (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) (defining "localized" cancers as "stage I-II")).

6376. The five-year survival rate for prostate cancer diagnosed when it is distant is 30 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (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) (defining "stage[s] I-III" as the stages "before distant metastases")).

4. Kidney Cancer

6377. Kidney cancer is one of the cancer types for which Grail claims Galleri can detect a signal. (*See* Bishop (Grail) Tr. 1374-75; RX2770 at 001 (2021 ASCO CCGA Poster)).

6378. The CCGA-3 substudy reports Galleri's sensitivity in detecting kidney cancer as 18.2 percent. (RX3409 at 007, Figure 3 (Klein, et al., Clinical validation of a targeted methylation-based multi-cancer early detection test using an independent validation set, 2021); RX2770 at 001 (2021 ASCO CCGA Poster)).

6379. Galleri detected a cancer signal for 6 of 77 participants in the CCGA-3 substudy with Stage I-III kidney cancer. (RX3773 at 039, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA)).

6380. Galleri's sensitivity for Stage I-III kidney cancer in the CCGA-3 substudy was 7.8%. (*See* RX3773 at 039, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (6 test positives for Stage I-III kidney cancer out of 77 participants in the substudy with Stage I-III kidney cancer)).

6381. Galleri failed to detect 92.2% of instances of early-stage kidney cancer in the CCGA-3 substudy. (*See* RX3773 at 039, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA) (6 test positives for Stage I-III kidney cancer out of 77 participants in the substudy with Stage I-III kidney cancer); *see* Ofman (Grail) Tr. 3430)).

6382. The five-year survival rate for kidney cancer diagnosed when it is local is 93 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* PX0086 at 001 (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) (defining "localized" cancers as "stage I-II")).

6383. The five-year survival rate for kidney cancer diagnosed when it is distant is 12 percent. (RX3030 at 023, Table 8 (American Cancer Society, Cancer Facts & Figures 2019); *see* 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) (defining "stage[s] I-III" as the stages "before distant metastases")).

5. The CCGA-3 Substudy Does Not Report Cancer Stages for 37 of 51 AJCC Cancer Types for Which Grail Claims Galleri Can Detect a Signal

6384. The CCGA-3 substudy does not report Galleri's sensitivity at detecting Stage I-III cancers for 37 of the 51 AJCC cancer types for which Grail claims that Galleri can detect a signal. (RX3773 at 038-41, Table S5 (Liu, et al., Sensitive and Specific Multi-cancer Detection and Localization Using Methylation Signatures in Cell-free DNA)).

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

6385. [redacted] (Ofman (Grail) Tr. 3416 (*in camera*)).

6386. [redacted] (Ofman (Grail) Tr. 3416 (*in camera*)).

6387. A November 2020 investment research report produced by Grail explained that "None of GRAIL's studies represent a truly prospective, real-world study. 70% of PATHFINDER enrollment is from an 'elevated risk group.'" The report concluded that "GRAIL Might Need to Run a New Study to Submit a PMA for Asymptomatic Patients." (PX4178 (Grail) at 025, Nephron Healthcare Investment Research, "Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly," Nov. 9, 2020).

6388. Hans Bishop, Grail's CEO, testified that "[t]here are some rare cancers that we [don't] yet have sufficient data on which to make performance claims," and that "there are cancers that we have insufficient data on which to say we can detect them today." (Bishop (Grail) Tr. 1375).

6389. [redacted] (Ofman (Grail) Tr. 3416-17 (*in camera*)).

6390. Kevin Conroy, Chairman and Chief Executive Officer ("CEO") of Exact Sciences, described [redacted]

[redacted]

(Conroy (Exact) Tr. 1578 (*in camera*)).

6391. Dr. Ofman, Grail's CMO, testified [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

(Ofman (Grail) Tr. 3333-34 (*in camera*)).

6392. Dr. Ofman testified at trial that Grail [redacted] } (Ofman (Grail) Tr. 3416-17 (*in camera*)).

6393. Nephron Healthcare Investment Research conducted what it described as a "comprehensive review of clinical data for early detection tests for pan-cancer screening" and published a report on Grail's clinical data in 2020, concluding that "GRAIL's clinical data has shortcomings." (PX4178 (Grail) at 005 (Email from S. Alag, Grail, to A. Chen, Grail, attaching Illumina – Downgrade to Sell: In the Search for the Holy GRAIL, We Think ILMN Chose Poorly, Nov. 12, 2020)).

6394. [redacted] (Ofman (Grail) Tr. 3335-36 (*in camera*)).

COMPLAINT COUNSEL'S PROPOSED CONCLUSIONS OF LAW

I. THE FEDERAL TRADE COMMISSION HAS JURISDICTION

1. The Federal Trade Commission ("FTC") has jurisdiction over the subject matter of this proceeding pursuant to Section 5 of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 45, and Section 7 of the Clayton Act, 15 U.S.C. §§ 18, 21(b).

2. The Commission has jurisdiction over Respondent Illumina, Inc. ("Illumina").

3. Respondent Illumina, Inc. is, and at all times has been, a corporation as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and also a person as defined in Section 1 of the Clayton Act, 15 U.S.C. § 12, and in Section 7 of the Sherman Act, 15 U.S.C. § 7.

4. The Commission has jurisdiction over Respondent GRAIL, Inc. ("Grail").

5. Respondent Grail is, and at all times has been, a corporation as defined in Section 4 of the FTC Act, 15 U.S.C. § 44, and also a person as defined in Section 1 of the Clayton Act, 15 U.S.C. § 12, and in Section 7 of the Sherman Act, 15 U.S.C. § 7.

6. The FTC is an administrative agency of the U.S. Government established, organized, and existing pursuant to the FTC Act, 15 U.S.C. § 41 *et seq* (2006). The FTC is vested with the authority and responsibility for enforcing, *inter alia*, Section 7 of the Clayton Act, 15 U.S.C. § 18, and Section 5 of the FTC Act, 15 U.S.C. § 45.

7. Respondents, including their relevant operating subsidiaries, are, and at all relevant times have been, engaged in activities in or affecting "commerce" as defined in Section 4 of the FTC Act, 15 U.S.C. § 44 (2006), and Section 1 of the Clayton Act, 15 U.S.C. § 12 (2006).

II. THIS ACQUISITION VIOLATES SECTION 7 OF THE CLAYTON ACT

8. Section 7 of the Clayton Act avers that "[n]o person . . . shall acquire [stock or assets] . . . where in any line of commerce . . . in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly." 15 U.S.C. § 18 (2012).

9. Section 5 of the FTC Act proscribes "[u]nfair methods of competition in or affecting commerce . . . ." 15 U.S.C. § 45(a)(1).

10. An acquisition that violates Section 7 of the Clayton Act, by definition, is a violation of Section 5 of the FTC Act. *See, e.g.*, *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986).

11. Section 7 of the Clayton Act applies to all mergers, which "must be tested by the same standard, whether they are classified as horizontal, vertical, conglomerate, or other." *FTC v. Procter & Gamble Co.*, 386 U.S. 568, 577 (1967).

12. "Economic arrangements between companies standing in a supplier-customer relationship are characterized as 'vertical.'" *Brown Shoe Co. v. United States*, 370 U.S 294, 323 (1962).

13. Courts and the Commission have traditionally analyzed Section 7 claims under a burden-shifting framework outlined in *Baker Hughes* and its progeny, *see United States v. Baker Hughes, Inc.*, 908 F.2d 981, 982-83 (D.C. Cir. 1990); *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 5957363, at *11 (F.T.C. Nov. 1, 2019); *In re Polypore Int'l, Inc.*, Docket No. D-9327, 2010 WL 9549988, at *9 (F.T.C. Nov. 5, 2010), and the same burden-shifting framework applies to both horizontal and vertical mergers. *See United States v. AT&T, Inc.*, 310 F. Supp. 3d 161, 191 n.17 (D.D.C. 2018) (rejecting, "as a matter of law and logic," defendants' assertion that the Section 7 burden-shifting framework is inapplicable to vertical merger cases such that the Government "has the burden to account for all of defendants' proffered efficiencies as part of making its prima facie case").

14. Under this burden-shifting framework, "[f]irst, the government must establish a prima facie case that an acquisition is unlawful." *Polypore Int'l*, 2010 WL 9549988, at *9; *see also Baker Hughes,* 908 F.2d at 982.

15. The Government's burden of production at this stage is low. The Government need only provide evidence "sufficient to raise an inference [of anticompetitive effect] to shift the burden to Respondent[s] for rebuttal." *In re Otto Bock HealthCare N. Am., Inc.*, 2019 WL 2118886, *27 n.25 (F.T.C. May 6, 2019) (Chappell, A.L.J.).

16. "The burden of producing evidence to rebut [the *prima facie* case] then shifts to the defendant." *Baker Hughes*, 908 F.2d at 982.

17. "If the defendant successfully rebuts the [*prima facie* case], the burden of producing additional evidence of anticompetitive effect shifts to the government, and merges with the ultimate burden of persuasion, which remains with the government at all times." *Baker Hughes*, 908 F.2d at 983.

18. Although Complaint Counsel has the ultimate burden in this case, Respondents bear the burden of proving their factual propositions. Initial Decision, *In re Altria Group, Inc. and Juul Labs, Inc.*, Docket No. 9393, at 5 (F.T.C. Feb. 15, 2022) ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.") (quoting 16 C.F.R. § 3.43(a)).

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

19. The Supreme Court has recognized that Section 7 prohibits acquisitions that may "substantially lessen competition within the area of effective competition." *Brown Shoe*,

370 U.S. at 324 (quoting *United States v. E.I. du Pont de Nemours & Co.*, 353 U.S. 586, 593 (1957) (internal quotations omitted).

20. To determine the "area of effective competition," courts "reference . . . a product market (the 'line of commerce') and a geographic market (the 'section of the country')[.]" *Brown Shoe*, 370 U.S. at 324. "Often, the first steps in analyzing a merger's competitive effects are to define the geographic and product markets affected by it." *ProMedica Health Sys., Inc. v. F.T.C.*, 749 F.3d 559, 565 (6th Cir. 2014). Whether the transaction at issue is horizontal or vertical, courts use the same set of analytic tools to define the affected market. *See Brown Shoe*, 370 U.S. at 324-28.

21. It is well settled that "the boundaries of the relevant market must be drawn with sufficient breadth to . . . recognize competition where, in fact, competition exists." *Brown Shoe*, 370 U.S. at 326.

22. A product market's "outer boundaries" are determined by the "reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *FTC v. Tronox Ltd.*, 332 F. Supp. 3d 187, 198 (D.D.C. 2018) (quoting *Brown Shoe*, 370 U.S. at 325).

23. To make this determination, courts generally look to two types of evidence: "the 'practical indicia' set forth by the Supreme Court in *Brown Shoe*, and testimony from experts in the field of economics." *FTC v. Sysco Corp.*, 113 F. Supp. 3d 1, 27 (D.D.C. 2015).

24. In *Brown Shoe,* the Supreme Court identified a series of "practical indicia" courts should consider in determining the relevant product market. The indicia include "industry or public recognition of the [market] as a separate economic entity, the product's peculiar characteristics and uses, unique production facilities, distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Brown Shoe*, 370 U.S. at 325; *see also Otto Bock*, 2019 WL 2118886, at *5 (Chappell, A.L.J.); *Sysco* 113 F. Supp. 3d at 27; *United States v. Aetna, Inc.*, 240 F. Supp. 3d 1, 21 (D.D.C. 2017); *United States v. H&R Block*, 833 F. Supp. 2d 36, 51 (D.D.C. 2011). Together, these practical indicia identify MCED tests as a distinct product market for purposes of assessing the Acquisition's competitive effects. *See* (CCFF ¶¶ 688-821).

25. Not all of *Brown Shoe*'s practical indicia are required to find a relevant market. *See Int'l T. & T. Corp. v. General T. & E. Corp.*, 518 F.2d 913, 932-33 (9th Cir. 1975) ("These indicia were listed with the intention of furnishing practical aids in identifying zones of actual or potential competition rather than with the view that their presence or absence would dispose, in talismanic fashion, of the submarket issue. Whether or not a court is justified in carving out a submarket depends ultimately on whether the factors which distinguish one purported submarket from another are 'economically significant' in terms of the alleged anticompetitive conduct.").

26. Along with the practical indicia set out in *Brown Shoe*, courts commonly use the hypothetical monopolist test to assess the relevant product market. *See FTC v. Advocate Health Care Network*, 841 F.3d 460, 468-69 (7th Cir. 2016) (applying the hypothetical monopolist test to define a relevant geographic market); *see also FTC v. Penn State Hershey Med. Ctr.*, 838 F.3d 327, 338 (3d Cir. 2016); *In re ProMedica Health Sys., Inc.*, 2012 WL 1155392, at *14 (F.T.C. Mar. 28, 2012); *Sysco*, 113 F. Supp. 3d at 33; *H&R Block,* 833 F. Supp. 3d at 51-52; *Horizontal Merger Guidelines* § 4.1.1.

27. Under the hypothetical monopolist test, a candidate market constitutes a relevant antitrust market if a hypothetical monopolist could profitably impose a "small but significant and non-transitory increase in price" ("SSNIP"), or reduce quality or availability, on at least one product of the merging parties in the candidate market, or whether customers switching to alternative products would make such a price increase unprofitable. *See Horizontal Merger Guidelines* § 4.1.1; *see also Otto Bock*, 2019 WL 2118886, at *6 (Chappell, A.L.J.).

28. Products do not need to be identical to fall within the same product market. *See United States v. Energy Sols., Inc.*, 265 F. Supp. 3d 415, 436 (D. Del. 2017) (products comprising a relevant market "need not be identical, only reasonable substitutes"); *see also Hicks v. PGA Tour Inc.,* 897 F.3d 1109, 1122 (9th Cir. 2018) (holding that "claims of increased effectiveness" of certain products does not "place" those products "in a distinct market"); *Humana Inc. v. Mallinckrodt ARD LLC*, CV 19-06926, 2020 WL 3041309, at *4, n.2 (C.D. Cal. Mar. 9, 2020) (explaining "it is wrong" to suggest that because two products "are not identical" they are not in the same relevant product market).

29. Instead, as the Supreme Court explained in *Brown Shoe*, "the boundaries of the relevant market must be drawn with sufficient breadth . . . to recognize competition where, in fact, competition exists." *Brown Shoe*, 370 U.S. at 326. This is because the relevant product market is meant to reflect actual "business reality [] of how the market is perceived by those who strive for profit in it," and of where the competitive concerns may arise. *FTC v. Cardinal Health, Inc.,* 12 F. Supp. 2d 34, 46 (D.D.C. 1998) (quoting *FTC v. Coca-Cola Co.*, 641 F. Supp. 1128, 1132 (D.D.C. 1986), *vacated as moot*, 829 F.2d 191 (D.C. Cir. 1987)).

30. Here, all MCED test developers are pursuing the same goal of creating the best MCED test. Contrary to Respondents' claims, the evidence shows that MCED tests will ultimately be quite similar. But they are unlikely to be identical. In an innovative market, such as the MCED test market here, differentiation and new approaches are *attributes of competition*, not indicia of its absence. *See* (CCFF ¶¶ 1902-2606).

31. Based on the hypothetical monopolist test, *see* (CCFF ¶¶ 822-30), and the *Brown Shoe* practical indicia, *see* (CCFF ¶¶ 688-821), the relevant product market is the research, development, and commercialization of MCED tests ("MCED test market").

IV. THE UNITED STATES IS THE RELEVANT GEOGRAPHIC MARKET

32. The relevant market in which to assess the anticompetitive harms of the Acquisition necessarily includes the relevant geographic market, or the area of competition affected by the merger. *See Sysco*, 113 F. Supp. 3d at 48 ("[T]he proper question to be asked . . . [is] where, within the area of competitive overlap, the effect of the merger on competition will be direct and immediate.'" (quoting *United States v. Phila. Nat'l Bank*, 374 U.S. 321, 357 (1963)); *see also Advocate Health Care Network*, 841 F.3d at 476 (citing *Phila. Nat'l Bank*, 374 U.S. at 357); *see also Horizontal Merger Guidelines* § 4.2.

33. Regulatory requirements are a well-recognized factor in determining the scope of geographic markets. *Horizontal Merger Guidelines* §4.2. When "customers in the United States must use products approved by U.S. regulators," then "[t]he geographic market is defined around U.S. customers." *Horizontal Merger Guidelines* §4.2.2; *see also Otto Bock*, 2019 WL 2118886, at *5-6 (Chappell, A.L.J.); Complaint, *In re Össur Hf., Össur Am. Holdings, Inc., and College Park Indus., Inc.*, Docket No. C-4712, at 2-3 (F.T.C. May 28, 2020) (defining the relevant geographic market for a medical device as the United States); Complaint, *In re Stryker Corp. and Wright Med. Grp. N.V.*, Docket No. C-4728, at 2 (F.T.C. Dec. 17, 2020) (same).

34. The United States has unique regulatory, *see* (CCFF ¶¶ 831-50), and reimbursement, *see* (CCFF ¶¶ 851-77), realities that distinguish it from other areas in the world with respect to the sale of MCED tests. In the United States, the FDA is responsible for regulating and approving medical devices for their safety and effectiveness, as set forth in Section 201(h)(2) of the Federal Food, Drug, and Cosmetic Act. 21 U.S.C. § 321 (defining the term "device" to include "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals"); *see also Morgan v. Medtronic, Inc.,* 172 F. Supp. 3d 959, 965 (S.D. Tex. 2016) ("Congress enacted the [Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act 'MDA'] in 1976 and granted the FDA authority to regulate the safety and effectiveness of medical devices sold in the United States."). *See* (CCFF ¶¶ 510, 512, 831-50).

35. Here, the United States is the relevant geographic market in which to analyze the effects of the Acquisition because the United States has unique regulatory requirements, *see* (CCFF ¶¶ 831-50), and American physicians and patients require tests that are approved by U.S. regulators. *See* (CCFF ¶¶ 831-85).

V. ILLUMINA'S NGS INSTRUMENTS AND CONSUMABLES ARE RELATED PRODUCTS TO MCED TESTS

36. The Government need not prove that the related product constitutes a relevant antitrust market. *See Brown Shoe*, 370 U.S. at 325, 344 (finding a Section 7 violation when only a

relevant product market was shown); *du Pont*, 353 U.S. at 593-95 (same); *AT&T*, 310 F. Supp. 3d at 195-97, 226–27 (D.D.C.) (scrutinizing the "measure of customer loss" underpinning the Government's "increased-leverage theory" without requiring proof of the upstream firm's "'market power' in the programming market").

37. No court has held that the government must prove monopoly power in a related product market to prove that a merger violates the Clayton Act. Instead, the proper inquiry here is whether Illumina supplies related products on which Grail's rivals rely. *AT&T*, 310 F. Supp. 3d at 195-97 (D.D.C.) (finding relevant antitrust product market for downstream multichannel video distribution in which alleged harm from transaction would occur, but not defining a related antitrust product market around upstream programming).

38. Illumina's NGS instruments and consumables are related products to MCED tests, serving as critical inputs necessary to their development and commercialization. *See* (CCFF ¶¶ 925-1018).

VI. THE ACQUISITION HAS A REASONABLE PROBABILITY OF SUBSTANTIALLY LESSENING COMPETITION IN THE U.S. MCED TEST MARKET

39. The Acquisition has a reasonable probability of substantially lessening competition in the market for the research, development, and commercialization of MCED tests in the United States and cause harm to American consumers. *See* (CCFF ¶¶ 1019-1398, 2607-3569).

40. As the Supreme Court has explained, "[t]he primary vice of a vertical merger . . . is that, by foreclosing the competitors of either party from a segment of the market otherwise open to them, the arrangement may act as a clog on competition, which deprives rivals of a fair opportunity to compete." *Brown Shoe Co.*, 370 U.S. at 323-24 (internal quotations omitted).

41. Foreclosure in the vertical merger context can mean either "foreclosing competitors of [one party] from access to a potential source of supply, or from access on competitive terms." *Yankees Entm't & Sports Network, LLC v. Cablevision Sys. Corp.*, 224 F. Supp. 2d 657, 673 (S.D.N.Y. 2002); *see also Sprint Nextel Corp. v. AT&T, Inc.*, 821 F. Supp. 2d 308, 330 (D.D.C. 2011) (explaining rivals "paying more to procure necessary inputs" is the type of injury "that the antitrust laws were designed to prevent").

42. Long-standing court precedent has set forth a framework for evaluating whether a vertical merger violates Section 7 of the Clayton Act. Case law and economic literature have looked to whether the merged firm has the ability and incentive to harm downstream rivals when evaluating the legality of a vertical combination. *See, e.g., AT&T*, 310 F. Supp. 3d at 243-45 (D.D.C.) (analyzing whether AT&T had ability and incentive to foreclose or restrict rival video programming distributors' access to Time Warner content); *In re* Union Carbide *Corp.*, 59 F.T.C. 614, 1961 WL 65409, at *19 (1961) (Lipscomb, A.L.J.) (finding anticompetitive harm where the merged firm "has the power to exclude" competing producers from a segment of the market).

43. While "it is the power [to harm competitors] that counts, not its exercise," *Union Carbide,* 1961 WL 65409, at *19 (Lipscomb, A.L.J.), courts may examine a merged firm's incentives to foreclose the relevant market when considering whether there is the potential for competitive harm. *See, e.g.*, *Ford Motor Co. v. United States*, 405 U.S. 562, 568-71 (1972) (Because Ford "made the acquisition in order to obtain a foothold" in the aftermarket spark plug market, "it would have every incentive to . . . maintain the virtually insurmountable barriers to entry" in that market through foreclosure.); *AT&T*, 310 F. Supp. 3d at 243-45 (D.D.C.) (analyzing whether AT&T had the ability and incentive to foreclose or restrict rival video programming distributors' access to Time Warner content).

44. Although Respondents claim that Illumina's "long-standing and core strategy is to catalyze development and expansion of sequencing," *see* Answer at 7, when Illumina is vertically integrated, this objective is weighed against the impact on Illumina's own downstream sales when it determines its strategy. By doing this, Illumina is simply acting as any standalone profit-maximizing firm would; it is only that Illumina is spurred to do this *through* acquisition that runs afoul of the law. *See, e.g.*, *Copperweld Corp. v. Indep. Tube Corp.*, 467 U.S. 752, 768-69 (1984) (explaining, in a non-merger antitrust case, that when "two or more entities that previously pursued their own interests separately are combining to act as one for their common benefit" it "deprives the marketplace of the independent centers of decision making that competition assumes and demands").

45. As the trial record demonstrates, the Acquisition fundamentally alters Illumina's incentives towards its MCED test developer customers, giving Illumina ample motivation to exercise its power to disadvantage Grail's rivals both prior to their launch and post-commercialization. *See* (CCFF ¶¶ 3079-569).

46. MCED tests developers' expansive reliance on Illumina during research, development, and commercialization of MCED tests, as well as the many levers Illumina has to identify and disadvantage its rivals, provides Illumina with the ability to foreclose Grail's rivals. *See* (CCFF ¶¶ 2608-3078).

47. *Brown Shoe* and its progeny also provide that the determination of a merger's likely competitive effects may be based on an analysis of several specific factors. While only a subset of those factors may be relevant to the fact-specific inquiry of a given case, courts have held that "the Clayton Act will, of course, have been violated" when "the share of the market foreclosed is so large that it approaches monopoly proportions." *Brown Shoe*, 370 U.S. at 328-29; *United States v. American Cyanamid Co.*, 719 F.2d 558, 566 (2d. Cir. 1983); *Fruehauf Corp. v. FTC*, 603 F.2d 345, 352 (2d Cir.1979) (noting that there is no *per se* rule that potential foreclosure "amount[s] to a violation of § 7" without more, "except where the share of the market foreclosed reaches monopoly proportions"). A high degree of potential foreclosure, alone, could be sufficient to show a reasonable probability of competitive harm. *Id*. Here the Court does not have to rely on just that factor as it is corroborated by other factors such as "the nature and economic purpose of the arrangement" and escalating barriers to entry by new firms. *Brown Shoe*, 370 U.S. at 328-29, 333; *see also American Cyanamid*, 719 F.2d at 566; *Fruehauf*, 603 F.2d at 352-53; *U.S. Steel Corp. v. FTC*, 426 F.2d 592, 598-99 (6th Cir. 1970).

48. Although today Illumina is the only supplier of NGS platforms to Grail and its rivals, the Clayton Act does not require that there be complete foreclosure to run afoul of antitrust

laws. *See Brown Shoe*, 370 U.S. at 323 n.39 (citing S. Rep. No. 81-1775, at 4298 (1950)) (explaining that the goal of Section 7 is "to arrest restraints of trade in their incipiency and before they develop into full-fledged restrains violative of the Sherman Act."); *see also id.* at 328-29 ("[T]he tests for measuring the legality of any particular economic arrangement under the Clayton Act are to be less stringent than those used in applying the Sherman Act.").

49. The Supreme Court recognized that "the very nature and purpose of the arrangement" was a factor to examine to determine the legality of a vertical merger. *Brown Shoe*, 370 U.S. at 329; *see also U.S. Steel*, 426 F.2d at 599; *Fruehauf*, 603 F.2d at 353. For example, in *Ford Motor Co. v. United States*, the Supreme Court held that Ford "made the acquisition in order to obtain a foothold in the aftermarket" spark plug market and "[o]nce [Ford] established [a foothold], it would have every incentive to . . . maintain the virtually insurmountable barriers to entry" in that market by foreclosing manufacturers from selling to Ford. 405 U.S. at 568-71.

50. Courts have held that the creation or increase of entry barriers can militate in favor of prohibiting a vertical merger. *See U.S. Steel*, 426 F.2d at 605; *Ford Motor*, 405 U.S. at 568-71. As the Sixth Circuit explained in *U.S. Steel Corp. v. FTC*, such barriers can include "possible reliance on suppliers from a vertically integrated firm with whom [a new entrant in the relevant market] is also competing" and "the psychological 'fears' of smaller rivals competing with large integrated concerns." 426 F.2d at 605 (citing *Procter & Gamble*, 386 U.S. at 578).

51. Under the *Brown Shoe* framework, this Acquisition would substantially lessen competition in the market for the research, development, and commercialization of MCED tests in the United States and cause harm to American consumers. *See* (CCFF ¶¶ 1019-1398, 2607-3569).

a. The Acquisition Will Harm Innovation in the MCED Test Market

52. Anticompetitive harm under Section 7 includes harm to innovation. *See Otto Bock*, 2019 WL 5957363, at *2 (finding that the acquisition "is likely to cause future anticompetitive effects in the form of higher prices and less innovation"); Initial Decision, *Altria*, Docket No. 9393, at 97, 99-100 (analyzing harm to innovation competition, along with price and shelf space competition, as a potential effect of the investment agreement between the parties); *In re Polypore Int'l, Inc.*, 2010 WL 9434806, at *211 (F.T.C. Mar. 1, 2010) (Chappell, A.L.J.) (finding that in one market "innovation competition has been eliminated post-acquisition"); *In re R.R. Donnelley & Sons Co.*, No. 9243, 1995 WL 17012641, at *73 (F.T.C. July 21, 1995) (competitive harm under Section 7 may "include a prediction of adverse effects in competitive dimensions other than price—reductions in output, product quality, or innovation"); *see also Horizontal Merger Guidelines* § 6.4 (explaining that harm to innovation can be an anticompetitive effect of a merger). In fact, in *United States v. AT&T, Inc.*, the D.C. Circuit explained that it "does not hold that quantitative evidence of price increase is required in order to prevail on a Section 7 challenge. Vertical mergers can create harms beyond higher prices for consumers, including decreased product quality and reduced innovation." 916 F.3d 1029, 1045-46 (D.C. Cir. 2019).

53. Not only is the innovation competition in the MCED test market important to protect in and of itself, the Federal Trade Commission has recognized the special importance of protecting competition in emerging markets:

> While monopolies are to be abhorred wherever they appear, it is of particular importance that they be arrested in an infant industry which appears destined for far greater expansion and growth. Strong and vigorous competition is the catalyst of rapid economic progress. Any lessening of competition is therefore doubly harmful in a new industry since its inevitable effect is to slow down the growth rate of the industry.
>
> *Union Carbide*, 1961 WL 65409, at *35.

54. Grail and its MCED rivals are currently competing on the basis of innovation. *See* (CCFF ¶¶ 3639-68). This competition will benefit consumers in the form of more accurate and cost-effective MCED tests. *See, e.g.*, (CCFF ¶¶ 3644, 3650, 3652, 3658, 3661, 3665).

55. This vertical merger has reasonable probability of harming innovation competition for MCED tests. *See* (CCFF ¶¶ 3570-668).

b. The Acquisition Will Hamper Commercial Competition between MCED Tests

56. When analyzing the competitive harm to the commercialization of MCED tests, "the proper timeframe for evaluating the effects of the merger on future competition must be 'functionally viewed, in the context of its particular industry.'" *Aetna,* 240 F. Supp. 3d at 79 (internal citation omitted).

57. As this Court explained in *In re Altria Group, Inc. and Juul Labs, Inc.*, this means looking at whether competition "would have existed in the 'near future,'" where "near" is "defined in terms of the entry barriers and lead time necessary for entry in the particular industry." Initial Decision, *Altria*, Docket No. 9393, at 106, 111-12 (quoting *BOC Int'l, Ltd. v. FTC*, 557 F.2d 24, 29 (2d Cir. 1977)).

58. Grail and its rivals expect to compete vigorously on price, service, and performance once on the market. This commercial competition will ultimately lead to lower prices and improved products. This vertical merger has reasonable probability of harming this commercial competition. *See* (CCFF ¶¶ 3189-569).

59. Analysis of both Illumina's post-Acquisition ability and incentive and the *Brown Shoe* framework supports the same conclusion: Illumina's acquisition of Grail will likely result in harm both to current innovation competition in the MCED market and competition between the commercialized versions of Grail's Galleri and rival MCED tests. *See* (CCFF ¶¶ 1019-1398, 2607-3668).

60. Once Complaint Counsel establishes its *prima facie* case, the burden shifts to Respondents to rebut Complaint Counsel's fact-specific showing of potential competitive harm. *Baker Hughes*, 908 F.2d at 982.

VII. RESPONDENTS FAIL TO MEET THEIR BURDEN TO SHOW ENTRY WILL BE TIMELY, LIKELY, AND SUFFICIENT TO COUNTERACT THE COMPETITIVE HARM FROM THE ACQUISITION

61. Respondents bear the burden of providing evidence that "ease of entry" rebuts Complaint Counsel's *prima facie* case. *Otto Bock*, 2019 WL 5957363, at *12 (citing *FTC v. H.J. Heinz Co.*, 246 F.3d 708, 715 n.7 (D.C. Cir. 2001); *see also H&R Block*, 833 F. Supp. 2d at 73 (noting that defendants "carry the burden to show" that entry or expansion is sufficient "to fill the competitive void" that would result from the merger) (internal quotations omitted).

62. "The mere existence of potential entrants does not by itself rebut the anti-competitive nature of an acquisition." *Chi. Bridge & Iron Co N.V. v. FTC*, 534 F.3d 410, 436 (5th Cir. 2008).

63. Entry or expansion must be "'timely, likely, and sufficient in its magnitude, character, and scope' to counteract a merger's anticompetitive effects." *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171, 222 (D.D.C. 2017) (citations omitted).

64. In assessing whether entry is likely, courts often look to the history of entry, including the "inability of new firms to gain traction," to assess "how difficult it is for new entrants to compete on the same playing field as the merged firm . . . ." *Anthem*, 236 F. Supp. 3d at 222-24 (dismissing Dr. Robert Willig's "breezy assurances" that developing a provider network is "not a big barrier to entry or expansion") (citations and quotations omitted).

65. Respondents have not shown that entry is timely, likely, and sufficient to satisfy the strict requirements for MCED tests, and thus, fail to demonstrate that it would counteract the competitive harm from the Acquisition. *See* (CCFF ¶¶ 1212-1398, 5013).

VIII. RESPONDENTS FAIL TO MEET THEIR BURDEN TO DEMONSTRATE THAT THEIR PROPOSED EFFICIENCIES AND ANY OTHER ALLEGED PROCOMPETITIVE BENEFIT OFFSET THE COMPETITIVE HARM

66. The stronger the *prima facie* case "the greater [Respondents'] burden of production on rebuttal." *Polypore*, 2010 WL 9549988 at *9; *see also Heinz*, 246 F.3d at 725; *Baker Hughes*, 908 F.2d at 991.

67. Respondents bear the burden of producing "clear evidence showing that the merger will result in efficiencies that will *offset* the anticompetitive effects and ultimately benefit consumers." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *Penn State Hersey*, 838 F.3d at 350) (emphasis added); *see also Hackensack*, 2022 WL 840463, at *10; *accord* Initial Decision, *Altria Group*, Docket No. 9393, at 5 ("[C]ounsel representing the Commission . . . shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.") (quoting

16 C.F.R. § 3.43(a)). In assessing such efficiency claims, courts have applied strict standards in their review. *Heinz*, 246 F.3d at 720-21; *H&R Block*, 833 F. Supp. 2d at 890.

68. No court has held that EDM and efficiencies could immunize an otherwise anticompetitive merger. *See Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (observing that "[r]esearch does not reveal a case that permitted an otherwise unlawful transaction to proceed based on claimed efficiencies."); *see also Penn State Hershey*, 838 F.3d at 347-48 ("Contrary to endorsing [an efficiencies] defense, the Supreme Court has instead, on three occasions, cast doubt on its availability . . . . Based on [the Supreme Court's past statements] and on the Clayton Act's silence on the issue, we are skeptical that such an efficiencies defense even exists.") (citations omitted).

69. In assessing such efficiency claims, courts have applied strict standards in their review. *Heinz*, 246 F.3d at 720-21; *H&R Block*, 833 F. Supp. 2d at 890. Specifically, "the court must undertake a rigorous analysis of the kinds of efficiencies being urged by the parties in order to ensure that those 'efficiencies' represent more than mere speculation and promises about post-merger behavior." *Heinz*, 246 F.3d at 721; *see also FTC v. Wilh. Wilhelmsen Holding ASA*, 341 F. Supp. 3d 27, 72 (D.D.C. 2018); *FTC v. CCC Holdings, Inc.*, 605 F. Supp. 2d 26, 72-73 (D.D.C. 2009).

70. Assuming *arguendo* that the efficiency or EDM defense is even potentially available, Respondents would bear the heavy burden to show that their efficiencies and EDM claims are cognizable, meaning that they are "merger-specific efficiencies that have been verified and do not arise from anticompetitive reductions in output or service." *Horizontal Merger Guidelines* § 10; *see also Hackensack*, 2022 WL 840463, at *10-11; *Heinz*, 246 F.3d at 720; *FTC v. Staples, Inc.*, 190 F. Supp. 3d 100, 137 n.15 (D.D.C. 2016); *Sysco*, 113 F. Supp. at 82.

71. To substantiate each efficiency, Respondents would be required to demonstrate that "it is possible to 'verify by reasonable means the likelihood and magnitude of each asserted efficiency, how and when each would be achieved (and any costs of doing so), how each would enhance the merged firms' ability and incentive to compete, and why each would be merger specific." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *H&R Block*, 833 F. Supp. 2d at 89); *see also Hackensack*, 2022 WL 840463, at *10-11; *Horizontal Merger Guidelines* § 10.

72. To demonstrate merger specificity, Respondents would need to "present a type of cost saving that could not be achieved without the merger[.]" *Wilhelmsen*, 341 F. Supp. at 72; *see also Hackensack*, 2022 WL 840463, at *11 ("*i.e.*, the efficiencies cannot be achieved by either party alone").

73. Even verifiable, merger-specific efficiencies are no defense absent "clear evidence" that they "will offset the anticompetitive effects and ultimately benefit consumers." *Otto Bock*, 2019 WL 2118886, at *50 (Chappell, A.L.J.) (citing *Penn State Hersey*, 838 F.3d at 350). "The critical question raised by the efficiencies defense is whether the projected savings from the mergers are enough to overcome the evidence that tends to show that possibly

greater benefits can be achieved by the public through existing, continued competition." *Cardinal Health*, 12 F. Supp. 2d at 63*; see also Anthem*, 855 F.3d at 355–56 (affirming district court's rejection of the efficiencies defense "because the amount of cost saving that is both merger-specific and verifiable would be insufficient to offset the likely harm to competition"); *FTC v. Peabody Energy Corp.*, 492 F. Supp. 3d 865, 918 (E.D. Mo. 2020) ("[E]ven granting Defendants every dollar of their claimed efficiencies . . . and making the implausible assumption that they would pass every penny of those efficiencies on to their customers, Defendants' claimed efficiencies still would not offset the likely competitive harm to those same customers[.]").

74. Where, as here, Respondents have failed to produce evidence that merger-specific, verifiable efficiencies will "neutralize if not outweigh the harm caused by the loss of competition and innovation," *Anthem*, 855 F.3d at 369 (Millett, J., concurring), the purported efficiencies defense fails. *See* (CCFF ¶¶ 5014-966).

75. Respondents cannot, however, reliably quantify the claimed value of EDM or any efficiency resulting from the Acquisition. *See* (CCFF ¶¶ 5364-78, 5706-15, 5721-51, 5778-79, 5786-99, 5837-47).

76. Respondents have also failed to demonstrate that their claimed efficiencies and EDM are merger specific. *See* (CCFF ¶¶ 5379-408, 5631-74, 5678-705, 5752-77, 5800-47).

    Respondents also have not met their burden to show that efficiencies or EDM would be passed through to consumers. *See* (CCFF ¶¶ 5716-20, 5780-85).

77. Respondents have failed to demonstrate that EDM and efficiencies would offset the harm from this anticompetitive acquisition. *See* (CCFF ¶¶ 5364-78, 5706-15, 5721-51, 5778-79, 5786-99, 5837-47).

IX. RESPONDENTS FAIL TO MEET THEIR BURDEN TO SHOW THEIR PROPOSED REMEDY REPLACES THE COMPETITIVE INTENSITY LOST FROM THE PROPOSED ACQUISITION

78. Respondents "bear the burden of showing that any proposed remedy would negate any anticompetitive effects of the merger[.]" *Otto Bock,* 2019 WL 5957363, at *44 (quoting *Staples*, 190 F. Supp. 3d at 137 n.15 (D.D.C. 2016)).

79. The purpose of a remedy in Section 7 cases is "to restore competition lost through the unlawful acquisition." *Otto Bock*, 2019 WL 5957363, at *43.

80. Here, Respondents' Open Offer is a remedy proposal. *See, e.g.*, Mot. For Conference to Facilitate Settlement, *In re Illumina, Inc. and GRAIL, Inc.*, Docket No. 9401, at 6-7 (F.T.C. July 13, 2021) (characterizing the Open Offer as "a consent agreement with protections in place to address the FTC's purported concerns . . . ."). *See* (CCFF ¶¶ 4484-5012).

81. To meet their burden, Respondents must show that the Open Offer would "replac[e] the competitive intensity lost as a result of the merger." *Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72) (emphasis in original).

82. To meet its burden, it is insufficient that the remedy replaces some or most of the lost competition. Rather Respondents must show that the remedy completely "replac[es] the competitive intensity lost as a result of the merger." *Aetna*, 240 F. Supp. 3d at 60 (quoting *Sysco*, 113 F. Supp. 3d at 72).

83. Here, Complaint Counsel has shown that the Acquisition clearly runs afoul of antitrust laws. Accordingly, "all doubts as to remedy are to be resolved in [Complaint Counsel's] favor." *Otto Bock*, 2019 WL 2118886, at *54 (Chappell, A.L.J.) (quoting *United States v. E.I. du Pont de Nemours & Co.*, 366 U.S. 316, 334 (1961)); *Ford Motor*, 405 U.S. at 575.

84. As a federal court explained when enjoining a merger in which the parties made a behavioral commitment not to raise prices, "the mere fact that such representations had to be made strongly supports the fears of impermissible monopolization." *Cardinal Health*, 12 F. Supp. 2d at 67.

85. Respondents' post-merger incentives can compromise the efficacy of their proposed remedy. For example, in *United States v. H&R Block*, defendants pledged to maintain the same price of TaxACT, one of the merged firm's tax preparation software. The court found such a commitment to be unavailing, noting:

> Even if TaxACT's list price remains the same, the merged firm could accomplish what amounts to a price increase through other means. For example, instead of raising TaxACT's prices, it could limit the functionality of TaxACT's products, reserving special features or innovations for higher priced, HRB-branded products. The merged firm could also limit the availability of TaxACT to consumers by marketing it more selectively and less vigorously.
>
> *H&R Block*, 833 F. 2d at 82.

The *H&R Block* court recognized that when a merger decreases competition, the merged firm will find ways to capitalize on the lower competitive intensity by circumventing any specific commitments designed to prevent anticompetitive consequences.

86. Competitors in the relevant market are not immune from harm if they accept a supply agreement with the merged entity. To the contrary, "it can be a problem to allow continuing relationships between the seller and buyer . . . such as a supply arrangement or technical assistance requirement, which may increase the buyer's vulnerability to the seller's behavior." *Sysco*, 113 F. 3d at 77 (internal quotation marks and citations omitted).

87. Rather than "replac[ing] the competitive intensity" lost from the Acquisition, Respondents' attempted behavioral remedy only applies to a small fraction of the relevant market who signed the Open Offer and does not scratch the surface of reversing the Acquisition's anticompetitive harms.

88. The Open Offer does not change Illumina's incentives to foreclose Grail's rivals. *See* (CCFF ¶¶ 4175-93).

89. The Open Offer does not preclude Illumina from disadvantaging Grail's rivals. *See* (CCFF ¶¶ 4484-5012).

90. Neither Grail's monitors nor an independent auditor can effectively monitor Illumina's compliance with the Open Offer. *See* (CCFF ¶¶ 4843-927).

91. The Open Offer cannot be effectively enforced. *See* (CCFF ¶¶ 4928-50).

92. Due to the clear inadequacies of the Open Offer, along with the outstanding concerns of those actually subject to the terms of the Open Offer, Respondents' proposed remedy falls well short of meeting their burden.

X. THE PROPOSED ORDER IS WARRANTED

93. Illumina's acquisition of Grail violated Section 7 of the Clayton Act, 15 U.S.C. § 18. The Proposed Order is warranted to address competitive harms caused by the acquisition.

94. Complaint Counsel met its burden of proof in support of Count I of the Complaint.

95. Entry of the Proposed Order is necessary and appropriate to remedy and prevent the violations of law found to exist. *Jacob Siegel Co. v. FTC*, 327 U.S. 608, 611-13 (1946).

96. The Commission has broad discretion to select a remedy so long as it bears a "reasonable relation to the unlawful practices found to exist." *Jacob Siegel*, 327 U.S. at 611-13.

97. Both this Court and the Supreme Court have declared complete divestiture as "the usual and proper remedy where a violation of Section 7 has been found." *Polypore,* 2010 WL 9434806, at *256 (Chappell, A.L.J.) (citing *du Pont*, 366 U.S. at 329; *Ford Motor*, 405 U.S. at 573); *see also Otto Bock,* 2019 WL 5957363, at *45 (holding that "a complete divestiture of Freedom . . . is necessary to restore competition in the MPK market").

Dated: April 22, 2022

Respectfully submitted,

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COMPLAINT COUNSEL'S WITNESS INDEX

IN THE MATTER OF ILLUMINA, INC. AND GRAIL, INC.
DOCKET NO. 9401

COMPLAINT COUNSEL'S WITNESS INDEX

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William Getty	Senior Vice President of Commercial Screening Division	Guardant Health, Inc.	2480:10 - 2693:05	2528:01 - 2632:16	9/10/2021 - 9/13/2021	10-11
Michael Nolan	Chief Executive Officer	Freenome Holdings, Inc.	2693:22 - 2857:07	2746:01 - 2856:21	9/13/2021	11

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COMPLAINT COUNSEL'S EXHIBIT INDEX

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CERTIFICATE OF SERVICE

I hereby certify that on April 22, 2022, I filed the foregoing document electronically using the FTC's E-Filing System, which will send notification of such filing to:

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