# In the Matter of Illumina, Inc. and GRAIL, Inc. Docket No. 9401



Oral Argument by Complaint Counsel December 13, 2022



### Illumina Is the "Only Game in Town"

#### Mike Nolan, Freenome CEO:

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You testified on direct that as of now,

Freenome cannot switch to another NGS platform other
than Illumina; right?

A. Yeah. We just don't have -- see a suitable
substitute to meet our highest-level requirements.
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#### **Dr. Darya Chudova, Guardant SVP Technology:**

- 1 A. Illumina sequencers, as I mentioned earlier,
- 2 are the only game in town. There are other sequencers
- 3 on the market, but ultimately they don't perform
- 4 similarly. And the test has been optimized to work in
- 5 an Illumina environment.

Sources: CCFF 1155, 1126



### MCED Test Developers Rely on Illumina Extensively

#### **Bill Getty, Guardant SVP Commercial:**

#### **Technical Support:**

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and, you know, say simple things like, you know, "We can't get a technician out to your sequencers until next Friday" or "the Friday after," and that could create challenges around turnaround time and disappoint customers and therefore hurt us competitively.
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#### Supply:

- Q. If Illumina stops supplying Guardant with the
- 10 reagents that Guardant uses for its cancer-screening
- 11 tests, what would the impact be to Guardant's
- 12 cancer-screening business?
- 16 THE WITNESS: It would be nonexistent.

#### **Delayed Access to Technology:**

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development -- and they were able to share that
technology ahead with GRAIL, ahead of the other
companies in the space who are also going to be reliant
on that technology, it would give GRAIL a significant

head start on the development of, say, a next version
of that assay -- excuse me, test, I use those
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## MCED Test Developers Rely on Illumina Extensively

### **Bill Getty, Guardant SVP Commercial:**

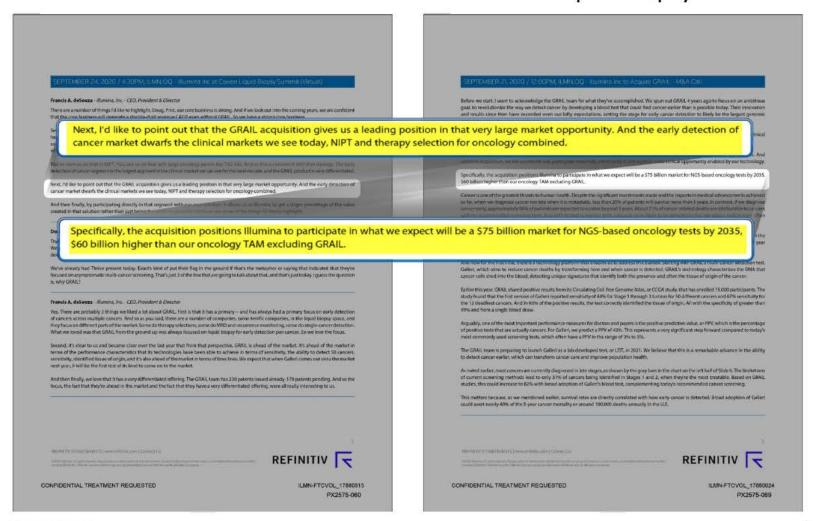
15	And so they are in a position where they could
16	take a significant advantage by kneecapping our ability
17	to run our lab, which would of course flow through to
18	our inability to compete in this larger blood-based

Source: CCFF 2844



### This Acquisition Gives Illumina The "Leading" Market Position

### Francis deSouza to investors at the 2020 Cowen Liquid Biopsy Summit:



Sources: CCFF 3136, 3139



# Other MCED Companies Are Developing Competitive Tests

MCED Developer	Similar Patient Population*	Similar Objective: Detect multiple early- stage cancers affecting large population segments	Blood-Based Test	Diagnostic Follow-Up (Identification of the TOO)	Established Commercialization Plans
Grail	CCFF 75-76,	CCFF 79, 377, 605, 669,	CCFF 77, 608-10,	CCFF 670,	CCFF 82-109,
Giali	378, 381, 712, 714	712	616, 3437	712, 3565-69	5271-5381
Exact/Thrive	CCFF 378, 381,	CCFF 414, 1938-40,	CCFF 1908, 1912,	CCFF 1963,	CCFF 1990-2014
	2159	2124-26	1936-37, 1940,	1966-68,	
			1942, 5999	3282, 3551-54	
Freenome	CCFF 378, 381, 717	CCFF 439-40, 443, 2355-	CCFF 439, 2363,	CCFF 2385,	CCFF 2368-69,
100 1111	2 118	56, 2373, 2375, 3537-38	2392	3555	2386-88
Guardant	CCFF 378; 381,	CCFF 377, 426,	CCFF 619-20, 641-	CCFF 2315-16,	CCFF 2285, 2294,
	716	430, 2274, 2277-78,	44, 935, 2258,	3299, 3549-50	2318-22
		3534-36	2343		
MCED #5	CCFF 420, 2217,	CCFF 420-22, 2211-12,	CCFF 2213, 2250,	CCFF 2236,	CCFF 2213, 2256
	2229	2221, 3541	2255	3548	
Singlera	CCFF 2422, 2463,	CCFF 447, 2418, 2421,	CCFF 448, 2418,	CCFF 2426,	CCFF 2434-41,
	2471	3539	2460	3556	2475-77
Helio	PX7077 at 30	CCFF 405-406, 455, 704,	CCFF 406, 454,	CCFF 2524	CCFF 2550-56,
		2513-15, 3363, 3542-44	2478, 2517		PX7077 at 81-82
MCED #8	PX7074 at 61, 204-	CCFF 377, CCFF 2564,	CCFF 2562,	PX7074 at 73	CCFF 2573-75,
	05	3545	PX7074 at 61-64		2591-94

<sup>\*(</sup>I.e., asymptomatic undiagnosed patients at average risk of cancer)



## **Ordinary Course Documents Show MCED Competition**

Selected Ordinary Course Evidence of MCED Competition			
PX2009 at 019	PX4027 at 001-04	PX4198 at 005	PX4450 at 241-42
PX2013 at 010	PX4037 at 008	PX4207 at 013, 033, 052	PX4456 at 002, 005, 012-13
PX2026 at 002	PX4046 at 094	PX4241 at 002, 005	PX4473 at 003, 005, 012
PX2031 at 005 n.2	PX4048 at 002, 004-07, 015	PX4250 at 003, 009, 011	PX4476 at 002, 004
PX2043 at 001	PX4049 at 001-03	PX4259 at 001	PX4519 at 001
PX2054 at 001-03, 05	PX4052 at 012, 039, 040, 044-45	PX4266 at 008, 045-046	PX4554 at 003-04, 008
PX2549 at 021	PX4053 at 001, 005	PX4267 at 009, 012, 032, 036, 048	PX4616 at 017, 030
PX2569 at 008	PX4054 at 008, 012	PX4284 at 012	PX6049 at 035-40
PX2575 at 064-65	PX4066 at 003	PX4288 at 001	PX8324 at 005
PX4006 at 001	PX4074 at 001, 099	PX4315 at 001	PX8368 at 079
PX4007 at 001-02	PX4075 at 009-10, 017, 027, 032-43, 046	PX4337 at 005-08	PX8458 at 001, 003
PX4011 at 003-005	PX4082 at 036	PX4340 at 004	PX8503 at 066
PX4016 at 006-07	PX4111 at 001	PX4350 at 001, 009	PX8530 at 003
PX4018 at 005-07	PX4129 at 001	PX4387 at 020, 043	PX8532 at 007
PX4021 at 001	PX4142 at 067	PX4441 at 002-04	PX8652 at 001
PX4023 at 001	PX4145 at 006, 009, 017, 021, 024, 033, 044	PX4442 at 001-03	PX8655 at 031
PX4025 at 001	PX4150 at 008, 032	PX4444 at 002, 009, 013	RX0894 at 24

Sources: CCFF 408, 697, 715, 759-60, 765, 772, 3189-3470, 3465-70, 3694-95.



# Ability to Foreclose a Monopoly Proportion of the Market "Of Course" Violates the Clayton Act

"If the share of the market foreclosed is so large that it approaches monopoly proportions, the Clayton Act will, of course, have been violated"

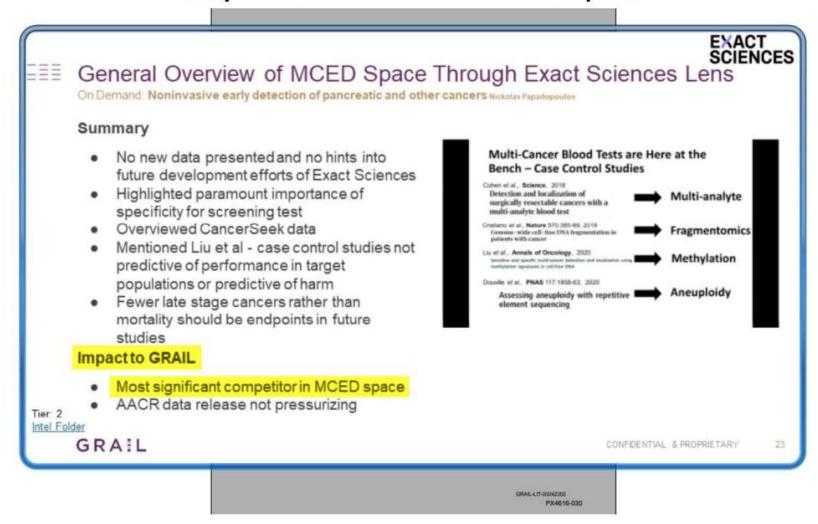
U.S. v. Brown Shoe, 370 U.S. 294, 328 (1962)

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### Competition Between Grail and Exact/Thrive

#### May 2021 Grail AACR Conference Report:



Source: CCFF 3231



# Grail and Exact/Thrive Are Neck and Neck in Development of an MCED Test

Exact/Thrive: Grail's "most significant competitor in [the] MCED space"

Exact/Thrive CancerSEEK		Grail Galleri
8	Number of early-stage cancers detected in asymptomatic patients	7
	Has undergone a prospective, interventional clinical trial	<b>✓</b>
	Has multiple published studies on its MCED test	
	Relies on Illumina NGS as a critical input	~
	Currently seeking FDA approval	
$\checkmark$	Currently developing next version of its MCED test	~
	Requires follow-up imaging tests to confirm cancer diagnosis	

Sources: CCFF 3231, 6298, 2031, 2015, 1054, 1085, 82, 109, 416



## Respondents' Open Offer Does Not Change Illumina's Incentives To Foreclose Grail's Rivals

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to be sure. But if the incentives aren't
           right, then the contract is not going to be
10
           successful in terms of promoting the business
           effectively for both parties.
11
12
                     "And, sure, the parties try to build
13
           in the protections that they think they can get
           into the contract, but the real details of how
14
           the business is going to work evolve from
15
16
           appropriate business incentives shared between
           the parties."
17
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### - Prof. Robert Willig, Expert for Respondents



## The Open Offer Fails To Eliminate Illumina's Ability To Harm Grail's Rivals

Illumina Lever	Inadequate/Unworkable Open Offer Provision	Major Loopholes
"Illumina Can	Illumina must supply any and all sequencing instruments	"A contract is only as good as it is enforceable. And
Completely Foreclose	and core consumables ordered by the customer in a	ultimately [Guardant's ability] to investigate
Grail's Rivals" (CC	timely manner. (PFF ¶¶ 1000, 1037; RRFF ¶¶ 2832,	adherence to the terms of that contract is nearly
Post-Trial Br. at §	2839, 2841, 2843, 2852, 2854, 2858.)	impossible." (CCFF 4804); see also (CCFF 4806-07;
II.E.1.a.ii.a)		4993-5012)
1000 0 10		The provisions in the Open Offer that relate to
"Illumina can impact		customer access to supplied products and
supply" (CC Post-Trial		customer pricing do not include access to or pricing of
Br. at II.E.1.a.ii.c)		library prep consumables. (CCFF 4553); see also (CCFF
		4528-31; 4533; 4536-40; 4543; 4553-54)
"Illumina can increase	Illumina cannot increase prices beyond inflation for the	Respondents' economic expert, Dr. Carlton, testified
prices" (CC Post-Trial	entire 12-year term of the Open Offer, until August 18,	that "GRAIL doesn't technically pay a price. If you want
Br. at § II.E.1.b)	2033. (PFF ¶¶ 1021–22; RRFF ¶¶ 2705, 4363.) Illumina	to make up a scenario in which you force GRAIL to
	must lower sequencing prices by at least 43% by 2025.	'pay some price,' and you call that a transfer price
	(PX0064 (Illumina) at 5; PFF ¶ 1023; RRFF ¶¶ 4363,	I'm happy to make that assumption." (CCFF 4652); see
	4658.) And if Illumina offers GRAIL or any other oncology	also (CCFF 4646-52; 4671-72])
	customer lower prices, it must offer those same lower prices to the customer. (PFF $\P\P$ 1017–18 RRFF $\P\P$ 2750, 4361–63.)	The Open Offer takes away discretionary discounts that were available to customers pre-Acquisition. (CCFF 4641-43).
		Illumina publicly announced plans to reduce sequencing costs 83 percent, much more than the 43 percent decrease in the Open Offer. (CCFF 4660-62,
		4655-4703). The 43 percent price decrease is the price
		per gigabase of sequencing, which is irrelevant to
		MCED test developers. (CCFF 4675-82)

Sources: Resp. Post-Tr. Reply Br. at 51; Compl. Counsel Post-Tr. Br. 89-94, 172-173.



# The Open Offer Fails To Eliminate Illumina's Ability To Harm Grail's Rivals

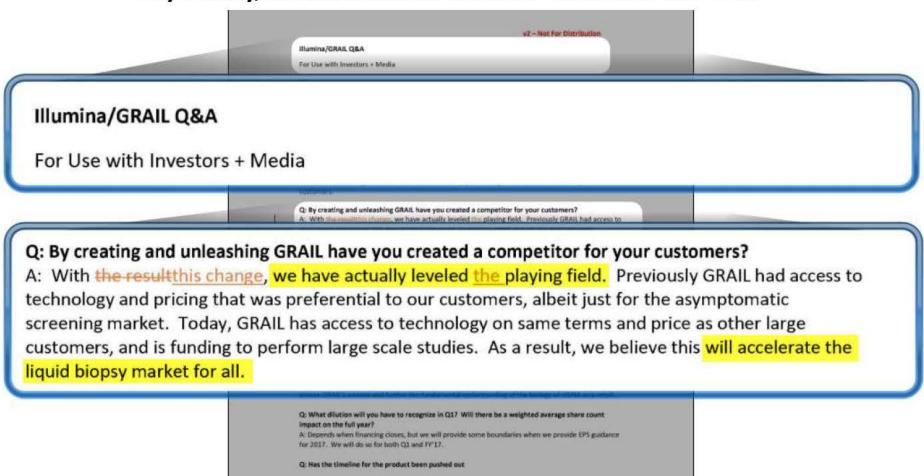
Illumina Lever	Inadequate/Unworkable Open Offer Provision	Major Loopholes
"Illumina can diminish	Illumina must supply the same levels of service and	"They [Illumina] could also, you know, one day turn
service and support"	support to the customer as it provided pre-merger and	around and, you know, say simple things like, you
(CC Post-Trial Br. at	as it makes available to GRAIL. (PFF ¶ 1004; RRFF ¶¶	know, 'We can't get a technician out to your
II.E.1.a.ii.d)	2855–57, 2868, 2871–73, 2878–93.)	sequencers until next Friday' or 'the Friday after,' and
		that could create challenges around turnaround time
		and disappoint customers and therefore hurt us
		competitively." (CCFF 2919); see also (CCFF 4495-
		4510; 4808-10; 4813; 4825-4842)
"Illumina can delay or	Illumina must provide the customer access to new	Illumina's Nicole Berry testified that the Open Offer
deny access to new	technology at the same time—within five days—as it	does not prevent Grail from having knowledge of
technology" (CC Post-	provides that technology to GRAIL. (PFF ¶¶ 1005, 1008;	Illumina's new technology before other companies.
Trial Br. at at	RRFF ¶¶ 2810–25.)	(CCFF 2810). Dr. Bert Vogelstein testified that
II.E.1.a.ii.e)		advanced knowledge of "future product
		developments and refinements" from Illumina "could
		substantially alter research and development in the
		field and the nature of the test products that are
		eventually produced." (CCFF 2813); see also (CCFF
		4594-4608)
"Illumina can develop	Upon customer request, Illumina must enter into a	When Illumina first formed Grail, it noted that
products specifically	development agreement on commercially reasonable	"Illumina understands the sequencer better than
for GRAIL" (CC Post-	terms relating to the design or modification of	anyone since they developed it and can in partnership
Trial Br. at II.E.1.a.ii.f)	sequencing products to optimize interoperability with	with [Grail] optimize i[t] for ctDNA applications
	the customer's tests. (See PFF ¶¶ 1005, 1008, 1010;	(e.g., improved error profile). This means that [Grail]
	RRFF ¶¶ 2825, 2830, 2986–97.)	can get better performance than someone who has to
		use the off the shelf version." (CCFF 2986); see also
		(CCFF 4609-14; 4545)

Sources: Resp. Post-Tr. Reply Br. at 51; Compl. Counsel Post-Tr. Br. at 94-99.



### Illumina's Spin-Off of Grail Leveled the Playing Field

#### Jay Flatley, former Illumina Executive Chairman and CEO:





### Selected Sources of Additional Evidence



## Illumina Is the Only Option for MCED Tests

MCED Developer	IH Testimony	Deposition Testimony	Trial Testimony
Grail	CCFF 1061, 1075-83, 2905	CCFF 1066, 1849-1852	CCFF 1057, 1071, 2902
Exact/Thrive	CCFF 1084, 1090, 1093-95	CCFF 1087, 1089, 2885	CCFF 929, 1084, 1087, 1091-92
Guardant	CCFF 1110, 1135, 1137, 1775	CCFF 1126, 1139, 4489	CCFF 1107-1108, 1116, 1129, 1130-34
MCED #4	CCFF 1104	CCFF 1099-1103	CCFF 1096-97, 1339
Freenome	CCFF 1151, 1157, 1159	CCFF 1143, 1150	CCFF 1140, 1145-46, 1727, 1729, 1155
Singlera	CCFF 1173-75	CCFF 1172, 1530	CCFF 1165, 1168, 2849
Helio	N/A	CCFF 1189, 1529	CCFF 1177-78, 1185, 1528
MCED #8	CCFF 1193, 1200	CCFF 3838-39, 4465	CCFF 1191, 1194-96

Sources: Compl. Counsel Post Tr. Reply Br. at 73-86; Compl. Counsel Post Tr. Br. at 66-79.



# MCED Test Developers Rely on Illumina at Every Stage of Development and Commercialization

Reliance During Research, Development,	Supporting Testimony
and Commercialization	
Collaboration	CCFF 2829-36, 2873-80
Custom-designed library prep products	CCFF 2613-14, 2987
Support/service	CCFF 2829-36, 2892-94, 2896-2900, 2918
Installation and technical support	CCFF 2805-09, 2880-91 2895
Dependable and reliable supply	CCFF 2830, 2837-54
Advance notice of new technology	CCFF 2813-17, 2820-24, 4598-9, 4605, 4559
Assistance in switching or upgrading to	CCFF 2736, 2805-07, 2887
new technology	
FDA approval process	CCFF 2946, 2948-49, 2951, 2954, 2956,
	2958-60, 2964-70, 2972-77, 4488-90



# Open Offer Fails To Alleviate MCED Developer Concerns

MCED Developer	Testimony
Exact/Thrive	CCFF 4184, 4399, 4501-02, 4536-37, 4540, 4627, 4672, 4730-31, 4745, 4749, 4823, 4852-57, 4874-75, 4930, 5005, 5007-12
Guardant	CCFF 4507, 4603, 4732-44, 4804-08, 4829-33, 4837-42, 4847-51,4876-78, 4938-41, 4962-65, 4993
MCED #3	CCFF 4178-79, 4485-86, 4528-34, 4613, 4670, 4685-86, 4693, 4708-11, 4729, 4747, 4809, 4844-45, 4929, 4933, 4997-5000
Freenome	CCFF 4189-90, 4504, 4579-83, 4633, 4636-37, 4834-35, 4846, 4994-96, 5006
Singlera	CCFF 4177, 4931
Helio	CCFF 4638, 4671
MCED #7	CCFF 4335, 4470-71, 4538-39, 4556-57, 4594-95, 4597, 4600, 4611-12, 4753, 4810, 4824, 5002



## Respondents' Efficiencies Are Inconsistent and Illogical

Respondents argue	But also	Source(s)
Grail needs Illumina for recruitment	Illumina spun off Grail to enhance Grail's ability to recruit	RPFF 68.4, 1669; CCFF 3723, 5026
Grail needs Illumina for R&D	Illumina spun off Grail for Grail to be "more nimble" in its R&D efforts	RPFF 1136-1145.9; CCFF 28, 31, 3722-23, 5756
Grail will collaborate closely across business units of Illumina	Illumina is able to maintain a firewall with Grail	RPFF 800.1, 1143.1, 1176.2, 1946; RPFF 1039.2-1039.3, 1041.3-1041.4
Grail needs Illumina's clinical testing experience	Illumina is not a clinical testing company but a clinical tools provider	Resp. Post-Tr. Br. at 191-92; PX2169 at 038
Illumina has no incentive to help Grail's market access absent the merger	Illumina has the incentive to expand NGS use today	Resp. Post-Tr. Br. at 226; 111- 12
EDM efficiency will lead to lower prices for customers	MCED test developers will not compete on price with Grail	RPFF 800.2, 1152.2; Resp. Post-Tr. Br. at 58-59