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Litigators of the Week: Cravath and Latham Defeat the FTC's Antitrust Challenge to Tie-Up Between **Illumina and GRAIL**

Chief Administrative Law Judge D. Michael Chappell rejected the FTC's position that the deal would hurt competition in the burgeoning market for multi-cancer early detection tests, handing a win to Illumina's team at Cravath and GRAIL's at Latham.

By Ross Todd September 9, 2022

Going to trial defending a merger before an administrative law judge at the U.S. Federal Trade Commission has typically been an against-all-odds sort of affair. Aside from the decision earlier this year in Altria's \$12.8 billion acquisition of a 35% stake in JUUL Labs Inc.-which wasn't a full-blown merger case—you can't find any such defense win.

That was until last week.

After a four-week trial, Chief Administrative Law Judge D. Michael Chappell rejected the FTC's challenge to Illumina's \$8 billion acquisition of GRAIL, which is developing a blood test for detecting more than 50 types of cancer. In doing so, the ALJ turned back the agency's position that the deal would hurt competition in the burgeoning market for multi-cancer early detection tests. (The European Commission, however, did announce it would block the deal this week—a decision Illumina said it would appeal.)

The ALJ's decision has earned "Litigator of the Week" honors for Illumina's team at Cravath, Swaine & Moore led by Christine Varney and David Marriott and GRAIL's team at Latham & Watkins led by Mike Egge and Al Pfeiffer.

Lit Daily: Who were your clients and what was at stake?

CRAVATH. SWAINE & MOORE LLP



Christine Varney, David Marriott of Cravath, Swaine & Moore

Mike Egge, Latham: Our client is GRAIL, a California-based biotech company that actually spun out of Illumina in 2016 as it pursued the "Holy Grail" of cancer—the detection of cancer in asymptomatic patients from a simple blood draw so they could catch it early and pursue a cure before symptoms and deadly spread—with the passion required to make a paradigm-shifting discovery. GRAIL discovered and developed Galleri, a test that detects up to 50 types of cancer.

What is at stake here is the vitality of a core free market model of accelerating biotech discoveries to market through partnership with companies with the

resources to take a life-saving discovery to as broad a market penetration as possible in the shortest time. The regulatory overreach in this case, and the harm it has caused and is causing today, is a travesty that affects every future cancer patient in the world, and we are pleased that the FTC's own home court, after a full trial on the merits, agreed.

Christine Varney, Cravath: We represented Illumina, a San Diego-based provider of DNA sequencing technology. Illumina acquired GRAIL, a cancer screening company originally founded by Illumina that has developed a test that can detect over 50 cancers with a simple blood draw. The FTC challenged the transaction as anti-competitive.

At stake was a transaction that, if permitted, will accelerate the widespread adoption of a cancer screening test, called Galleri, that will save lives. This case is also important to the development of antitrust law, as it is the FTC's first litigation regarding a vertical merger in over 40 years.

How did this matter come to the firm? And what other matters are you handling for your respective clients?

Egge: GRAIL's then-General Counsel was a former Latham associate and approached our partner Alex Voxman to have us support GRAIL in an IPO. That ultimately led to an acquisition by Illumina and Latham was tapped to handle every angle associated with the transaction, including antitrust, which is where I got involved. Christine Varney and I were intimately involved in the negotiation of the deal, for Illumina and GRAIL, respectively, and we worked arm-in-arm in devising a forward-looking strategy to win fast approval. Christine and I share the same philosophy of thinking creatively, ahead, to resolve issues rather than wait for them to arise. So in the interest of getting this life-saving test to market as quickly as possible, we proposed, from the very first interactions with the FTC, a gold-plated vertical remedy typical for these kinds of cases, but the FTC refused to even entertain it. The court made clear in its opinion here the remedy offered went above and

beyond since the FTC failed to show it had a credible case to begin with. We continue to represent GRAIL in the regulatory issues it and Illumina still face on appeal here, as well as in Europe.

Varney: Cravath represented Illumina in connection with its acquisition of GRAIL, where our corporate department handled the transaction, while our antitrust department dealt with regulatory aspects of the deal. Subsequently, Cravath also represented Illumina in connection with litigation brought by BGI alleging that Illumina's assertion of its sequencing patents was anti-competitive, which has now settled.

Who was on your teams and how did you divide the work?

Al Pfeiffer, Latham: With Latham's global platform and deep bench of experienced antitrust lawyers, we were able to bring to bear a large team with capabilities across multiple specialties. Mike spearheaded our representation of GRAIL from day one, leading and coordinating antitrust teams here in the U.S., and in Europe, with partner Maggy Sullivan also involved from the outset with the FTC in case this went to litigation. A key feature of our FTC practice is including our trial litigators as early in the process as possible. Once the FTC filed its suit to block the deal, first in federal court and then in their internal administrative court, I was tapped to take our team to trial, joined by Maggy and counsel Anna Rathbun and Monica Groat. We were supported by a team of rockstar associates at trial, including David Johnson, Sean Mulloy, Zoë Hutchinson, and Nathaniel Amann. And of course, this all started with our partners Alex and Andrew Clark, who guided a multi-specialty corporate and regulatory team to get the deal together in the first place.

David Marriott, Cravath: This was a true team effort. Given the mix of complex economic, antitrust and scientific issues involved in this case, we assembled a multi-disciplinary team of Cravath attorneys who worked on the case from the FTC's initial investigation to trial, with significant help from the in-house team at Illumina. Christine focused on the FTC strategy and led the development of Illumina's trial strategy.

I served as lead trial counsel, presenting Illumina's opening and closing argument and putting on key trial witnesses, such as Illumina's CEO and chief economist, as well as cross-examining the FTC's chief economist and many of the fact witnesses.

Our partner **Sharon Goswami**—a real rock star played a critical role in the case and at trial, putting on Illumina's technical and remedy experts and examining a number of crucial fact witnesses, including key Illumina and third-party witnesses. She has an uncanny ability to make the complicated understandable.

Of counsels Jesse Weiss and Michael Zaken were indispensable throughout the case. They know antitrust inside and out and are skilled trial lawyers.

Dozens of people from Illumina, including Charles Dadswell, Scott Davies, Roland Schwillinski and Steve Keane, provided key strategic guidance and support.

The merger challenge centered on a product that's not yet hit the commercial market. How did that affect the case and the defense you put on?

Egge: A core feature of the case is the fact that GRAIL's test, Galleri, is the first of its kind, with no likely competition in the near or even medium-term future, as no one has made a like discovery, much less started the clinical trials required to credibly take a product to market. This raised the very fundamental antitrust question: When is it ever appropriate to use antitrust enforcement to slow an invention to market so that, just maybe, others might catch up and make the "race" more interesting? I'd say never—we take our markets as they come, even with winners with long leads, and we bring their inventions to meet market demand without regulatory brakes based on speculation. Our courts agree with this view, thankfully.

Varney: The FTC brought this case despite the fact that GRAIL was the only company to have a multicancer screening test on the market. This fact was critical as it highlighted the speculative nature of the FTC's theory of harm. The FTC alleged that Illumina's acquisition would provide Illumina with the incentive to harm GRAIL's putative rivals. Our defense emphasized the fact that these alleged rivals were many years away from having a product on the market and that there could thus be no incentive for Illumina to harm these companies. The ALJ ultimately agreed with us.

What were your trial themes and how did you hammer them home with the ALJ?

Pfeiffer: From GRAIL's perspective, we focused on how the deal would help GRAIL, in very concrete ways, get its test to commercial acceptance faster—meaning it would save thousands of lives that would otherwise be lost to cancer. No other alternatives besides this merger would get us there nearly as quickly. And we also highlighted that the companies questioning about this deal were really just trying to slow GRAIL down because they were far behind; that's not the proper role of antitrust enforcement.

Marriott: We emphasized three key themes. First, the transaction provided the potential for enormous benefits because a reunited Illumina and GRAIL will accelerate the widespread adoption of Galleri and save thousands of lives. Second, the FTC's case was entirely speculative, as no company besides GRAIL had a test on the market. Third, to the extent there was any potential for harm (and there was not), Illumina had committed to resolve these concerns through a 12-year supply agreement commitment, known as the Open Offer, that addressed all hypothetical concerns raised by the FTC.

We incorporated these themes in every aspect of the trial from opening statement to closing. For example, Illumina's witnesses made clear that they had no incentive or ability to harm GRAIL's alleged rivals and presented the benefits of the transaction to the ALJ. We showed, through cross-examination, that third parties were not as close to commercialization as the FTC claimed and that their alleged concerns were unwarranted. We also assembled a highly qualified slate of experts, including medical doctors, cancer researchers, experts in regulatory approvals, audit experts and leading economists.

I gather that during the closing argument the ALJ was interested in how this litigation might affect the availability of the GRAIL test and whether lives were potentially at stake. What was your response?

Pfeiffer: Judge Chappell was very aware, from having heard the evidence at trial, that the companies raising issue with the deal were using the suit as a way to slow GRAIL down. And the evidence was undisputed that getting GRAIL to commercial acceptance and availability sooner would save many, many lives. When he asked, we told him that, and that the pendency of this lawsuit had already improperly slowed GRAIL down.

Marriott: There's no question the transaction, if allowed, will save lives. While GRAIL's test is very limited in its current availability, it won't achieve widespread adoption until it clears certain regulatory hurdles and is covered by Medicare and private insurers. Illumina has the ability to accelerate the widespread adoption of Galleri and will do so if and when the transaction clears. The FTC claimed that similar results could be achieved by other test developers in absence of the transaction. We demonstrated at trial that such tests were years away and that their potential to save lives was speculative at best. If you look at the development of cancer screening tests as a race, the only company currently on the track competing is GRAIL. Other tests are still at home warming up and it's entirely speculative whether they will be in the race at all.

The FTC has already indicated that it will appeal the ruling. What makes you think this result will hold up before the full commission?

Varney: The ALJ's ruling was based on a detailed assessment of the facts put forward by both sides and the credibility of each side's witnesses. The case put forward by the FTC did not withstand the evidence put forward by Illumina or cross-examination of the FTC's witnesses. Egge: At the end of the day, we're passionate about the lives GRAIL's technology will save and we will continue to vigorously share our client's story and defend their position as life-saving innovators in any court.

What will you remember most about this matter?

Egge: I will remember most the commitment of the GRAIL team to create a paradigm shift in cancer detection and thus treatment, and then find the fastest way to get their invention to as many people as possible. From top to bottom that has been their sole purpose and for me, having watched my own teenage daughter fight bone cancer over these past five years, the GRAIL team's vision and purpose gives me tremendous hope and inspiration. Cancer is so devastating—what the GRAIL team has done to help people get ahead of it is simply awesome.

Pfeiffer: I have known about GRAIL from its inception, from a friend who used to work there. To get the chance to work on matters that can truly, dramatically, make people's lives better—it's one of the most thrilling, and gratifying parts of this job. Getting the opportunity to support such an important cause, while working with an amazing team of lawyers around the world, is as good as it gets.

Varney: For me, it is the fact that the team was able to put together an entire case from initial investigation to four-week trial within the span of less than a year. We did all of this at an unprecedented speed and entirely remotely (including trial). This could not have happened without the aid of the entire Cravath team and an incredibly talented in-house team at Illumina.

Marriott: There's a lot to remember, including a spectacular client, a thoughtful judge, a group of talented FTC adversaries, great co-counsel at Latham, a set of compelling antitrust issues, and more. But top of the list for me is the chance to participate in a proceeding that has the potential to save and change many thousands of lives. A reunited Illumina and GRAIL would make the world a far better place.