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News We're Watching: Apple/Masimo Patent Fight Update; Acutus Winds Down; Illumina Bails On Grail

by Reed Miller

Medtech Insight's News We're Watching highlights medtech industry developments that you may have missed over the last few weeks. In addition to the big news from Acutus, Apple, and Illumina, Masimo scored an important FDA clearance, Beta Bionics announced the US launch of its iLet bionic pancreas for Dexcom's G7 CGM, and more.

Apple Stops Sales Of Certain Watches In Response To ITC Ruling

Under legal pressure from *Masimo*, *Apple* will stop selling the Apple Watch Ultra 2 and Apple Watch Series 9 in the US.

According to a report *9to5Mac*, a website devoted to Apple product news and reviews, those models of Apple Watch will disappear from Apple's US website after 3 PM ET on 21 December and will leave Apple retail locations after 24 December.

Apple is pulling the products from shelves to comply with a 26 October *International Trade Commission* (ITC) ruling – upholding an earlier preliminary decision – that determined that the pulse oximeter technology in these Apple watches violates two of Masimo's patents. The ITC issued a limited exclusion order and cease-and-desist order to block the import of these Apple Watches. (Also see "*News We're Watching: Apple Watch Imports Blocked, Fresenius Recall, Groups Ask For Longer LDT Comment Period*" - Medtech Insight, 27 Oct, 2023.)

The Apple Watch SE, which does not include the pulse-oximeter feature, is still available to consumers.

Apple told *9to5Mac* that it plans to file an appeal with the US Court of Appeals for the Federal Circuit on 26 December.

The Biden administration could veto the limited exclusion order within 60 days. The end of the 60-day window falls during the Christmas break so the administration could delay the decision, but if the order is not vetoed, it will go into effect, even if Apple's appeal is pending.

Only two such orders have been vetoed in the last 30 years and earlier this year, the President upheld an ITC ruling that Apple infringed wearable technology owned by AliveCor. (Also see "*Biden Administration Upholds ITC Ruling That Could Result In Apple Watch Ban*" - Medtech Insight, 22 Feb, 2023.)

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Based on discussions with patent law experts, BTIG analyst Marie Thibault expects the Biden administration will let the exclusion order take effect after Christmas.

Thibault believes Massimo will seek to "secure settlements, royalty payments, or other monetary-based agreements" from Apple.

In an 18 December note, Wells Fargo analyst Vik Chopra suggested that Apple will ask the ITC to or the appellate court to "freeze" the importation ban, which would make the ruling "easier" for Apple to appeal.

He also agreed with Thibault that Masimo now has leverage to seek an advantageous settlement with Apple, but Apple's decision to pull the devices from the market "presumably means that Masimo and Apple are far apart in their estimates of the settlement number."

"There is no royalty related to an ITC importation ban, [but] Masimo will try to use these patents to get a future court-ordered royalty in its pending patent case and will also try to negotiate a settlement with Apple based on that royalty threat, plus the cost to Apple of living with this importation ban."

Chopra also pointed out that although Apple could appeal the ITC's ruling, by the time the appeal is resolved, these models of Apple Watch will likely be obsolete anyway.

Illumina Moves Closer To Divesting Grail Despite Partial Court Victory

Illumina plans to divest its Grail liquid-biopsy subsidiary through a third-party sale or capital markets transaction by the end of the second quarter of 2024.

"We are committed to an expeditious divestiture of GRAIL in a manner that allows its technology to continue benefitting patients," Illumina CEO Jacob Thaysen said on 17 December. "The management team and I continue to focus on our core business and supporting our customers. I am confident in Illumina's opportunities and our long-term success." (Also see "*Minute Insight: Illumina Seeks Stability, Names Thaysen As New CEO*" - Medtech Insight, 6 Sep, 2023.)

Anti-trust regulators in the US and Europe have been telling Illumina to divest Grail ever since Illumina acquired it in 2020 for $8bn. Amid a leadership shakeup and investor discontent, the company tried to fight those regulatory decisions in court. (Also see "*News We're Watching: Illumina Looks At Grail Options, New AdvaMed Digital Health Division, Evolut FX Gets CE Mark*" - Medtech Insight, 13 Oct, 2023.)

In October, after the European Commission mandated that Illumina sell Grail, the company conceded it was investigating its options for divesting Grail if it ran out of options for keeping it. The company again signaled its plans to divest Grail earlier in December by filing a draft registration statement with the US Securities and Exchange Commission. (Also see "*Minute Insight: The Illumina-Grail Dream Is Over... In Europe*" - Medtech Insight, 12 Oct, 2023.)

> ***"Illumina's decision to unwind its acquisition of Grail ensures the market for cancer detection tests remains competitive and delivers a choice of high-quality tests for patients and physicians, ultimately saving lives." – Henry Liu***

The company decided to exercise one of those divestment options even though, though it scored a partial victory in a US court.

On 15 December, *the US Fifth Circuit Court of Appeals determined* that the US Federal Trade

Commission proved that the Illumina-Grail merger would probably constrain competition in the market for the research, development, and commercialization of multi-cancer detection tests. The court also rejected the company's argument that the FTC had unconstitutionally exercised its power by trying to block. this merger.

However, the court also determined that the FTC applied the wrong legal standard in its ruling.

The Clayton Antitrust Act prohibits mergers that will "substantially" lessen competition in a particular market. Illumina tried to comply with that part of the law by creating an "open offer" to continue supplying its next-generation sequencing technology to Grail's competitors at the same price and service level that it provides to Grail.

The court concluded that the law required Illumina to show that the merger would not "substantially" reduce competition in the market, while the FTC was insisting that the company show that the proposed merger would "not lessen competition at all."

"This was a legal error," according to the court. "Illumina was only required to show that the open offer sufficiently mitigated the merger's effect such that it was no longer likely to substantially lessen competition. Illumina was not required to show that the open offer would negate the anticompetitive effects of the merger entirely."

But while the court vacated FTC's order and remanded it for further proceedings, Illumina has elected not to pursue further appeals of the Fifth Circuit's decision.

Even though the court vacated its order, the FTC declared victory.

"This is a major win for the FTC as it works to protect competition in health care," FTC director Henry Liu said in a prepared statement. "Illumina's decision to unwind its acquisition of Grail ensures the market for cancer detection tests remains competitive and delivers a choice of high-quality tests for patients and physicians, ultimately saving lives."

Illumina is unlikely to sell Grail for anything close to the $8bn it paid for it in 2020, but the stock market clearly wants the company to divest it. Illumina's share price on NASDAQ dropped below $93 in early November before rebounding past $130 in mid-December.

On 18 December, Canaccord Genuity analyst Kyle Mikson wrote, "Considering the current capital markets outlook for 1H24 appears bleak, we believe the ultimate terms of the divestiture may not be ideal (or may not materialize by 2Q24)."

However, Wall Street analysts agree that Illumina had no choice but to divest Grail – the sooner, the better. "The separation is an important action and should be completed even if the terms are

not highly favorable," Mikson wrote.

Mikson pointed out that Illumina's challenge of the European Commission's jurisdiction over the merger is still alive in the European Court of Justice. The outcome of that case will not change the company's decision to divest Grail, but "the outcome may affect the company's specific plans to divest Grail," he wrote.

According to Leerink Partner's Puneet Souda, Illumina is in discussions with the EC about the capitalization requirements for Grail. "In the case of a spin-off, Illumina would need to capitalize Grail for two and a half years of funding, while an outright sale would have no capitalization requirement. Illumina continues to pursue both paths in parallel," Souda wrote on 11 December, shortly after Illumina filed the draft registration statement with the US SEC.

Acutus Will Just Focus On Medtronic Left-Heart Access Business

Acutus Medical has dropped its electrophysiology mapping and ablation business to direct all of its remaining resources on making left-heart access devices for *Medtronic*.

Acutus began letting go of 65% of its workforce and cutting operating expenses in early November. That process will be completed in the first quarter of 2024, Acutus said.

The California company supported its AcQMap electrophysiology mapping products with a small team of therapy managers through end of November, but now it is “winding down” all of that business, including the AcQMap mapping system, the AcQMap 3D mapping catheter, the AcQBlate force-sensing ablation catheter, the AcGuide Max 2.0 steerable sheath, and associated accessories.

Acutus was also one of the companies developing a pulsed-field ablation system, but that appears to be history as well. (Also see "*First PFA In The US: FDA Approves Medtronic’s PulseSelect For AF Ablation*" - Medtech Insight, 14 Dec, 2023.)

Medtronic bought Acutus’ left-heart access portfolio in 2022. Under the terms of that deal, Acutus has continued to manufacture the left-heart access devices, but Medtronic plans to eventually manufacture those devices on its own. (Also see "*Minute Insight: Acutus Adds Another Device To The Left-Heart Business It Sold To Medtronic*" - Medtech Insight, 27 Jun, 2022.)

Acutus’ now board hopes the company will become a profitable contract-manufacturing business.

> *"We have concluded that the optimal use of the company's resources is to reallocate capital from our mapping and ablation business to the manufacturing of left-heart access products for Medtronic." – Scott Huennekens*

"In light of the current financing environment and the capital investments required to achieve leadership in the electrophysiology market, we have concluded that the optimal use of the company's resources is to reallocate capital from our mapping and ablation business to the manufacturing of left-heart access products for Medtronic, which we believe will maximize the potential for future earnouts and cash flow," Acutus chairman Scott Huennekens said.

Many analysts and electrophysiologists are impressed with Acutus' electrophysiology mapping technology, but it struggled to convince enough electrophysiology labs to adopt it. (Also see "*Acutus Names David Roman As New CEO; Mickelsen Departs Company*" - Medtech Insight, 21 Jul, 2022.)

Acutus went public in 2020 and its stock peaked soon thereafter at $34.20. It has been mostly downhill since then and Acutus shares are now trading around $0.20.

In 2022, the company cut its workforce, changed its leadership and announced a new plan to focus on a select group of high-volume customers. And, as recently as August, CEO David Roman was projecting optimism about the growth in AcQMap procedure volumes and the company's plans to reach profitability, but there was not enough progress to keep the electrophysiology business afloat.

In the third quarter of 2023, the company reported 44% year-over-year revenue growth, but revenue in the quarter only amounted to $5.2m and most of that was from its arrangement with Medtronic. The net loss in the quarter was $13.2m.

"The realignment of resources and corporate restructuring unfortunately impacts our team. It is undoubtedly difficult to part with our valued and highly talented colleagues who have made substantial contributions to our company," Roman said. "I want to thank each one of them for their dedication to Acutus and our mission."

Verigraft Hopes To Bolster Its Tech With AI

Swedish tissue therapy company Verigraft, which is working on a range of personalized venous and vascular grafts, is hoping that artificial intelligence will spot links in data that humans otherwise cannot.

The company's new project, which will run until 2026 will collect data about graft recipients' genomes, cellular make-up, and protein levels both before and after procedures are performed.

This data will train artificial intelligence models in a bid to recognize and understand underlying patterns in the data – hopefully generating insights beneficial for predicting manufacturing quality and patient outcomes.

Verigraft CEO Petter Björquist said that "the data gathered in this project will also help us move towards 3D printing of graft scaffolds" - part of the company's bold product pipeline. (Also see "*VERIGRAFT Is Taking A Fresh Approach To Personalized Tissue Grafting*" - Medtech Insight, 18 Sep, 2023.)

Beta Bionics Launches iLet Pump For Dexcom G7 CGM

Beta Bionics launched its iLet Bionic Pancreas automated insulin delivery system for Dexcom's G7 continuous glucose monitor throughout the US on 18 December.

A firmware update allows users to update their existing iLet devices to integrate with a G7 without any new hardware, the company announced on 7 December. Existing iLet users will be able to download the update from the Apple App store or Google Play store.

The iLet Bionic Pancreas is an autonomous insulin delivery system that can help patients manage their insulin by just entering their weight. Its algorithm-controlled dosing decision software controls the rest of the complicated calculations needed to determine appropriate insulin dosing.

The US Food and Drug Administration cleared iLet in May. The Massachusetts company secured $100m in financing to support its commercialization in August. (Also see "*Beta Bionics Secures $100M In Series D Funding To Expand Artificial Pancreas Tech*" - Medtech Insight, 31 Aug, 2023.)

"Once we established our timeline, we were able to rapidly integrate, test and launch with Dexcom G7 in only four months," Beta Bionics CEO Sean Saint said. "It's a clear testament to our teams working in unison with a common goal of providing the latest technology to help users manage their diabetes with less work and less burden."

Dexcom CEO Jake Leach said, "Dexcom G7 was designed with connectivity in mind and this

latest integration with Beta Bionics is a testament to that."

Fresenius Announces Biggest Deal For Ivenix Infusion Pumps

Fresenius Kabi signed a multiyear agreement to sell 10,000 Ivenix large-volume infusion pumps to Mayo Clinic's hospitals and clinics in Minnesota, Arizona and Florida.

Ivenix is a "smart pump" that interfaces with hospital information systems and electronic medical records.

The deal, announced on 14 December, is the largest contract for Ivenix pumps, according to Fresenius Kabi.

Earlier this year, Fresenius announced a new strategic plan for its Kabi unit to focus on products for critically and chronically ill patients, while developing new growth opportunities. (Also see "*Fresenius Brings In Transparency Change For Kabi Unit*" - Generics Bulletin, 18 May, 2023.)

Wells Fargo analyst Larry Biegelsen believes this deal shows Fresenius Kabi's potential strength in the infusion market. "We don't expect any real impact in the near term but believe longer term Ivenix becomes a viable full line competitor to Baxter and an alternative to Becton Dickinson."

Masimo Releases Prescription Stork

The US Food and Drug Administration *cleared Masimo's Stork* prescription baby monitoring system for babies up to 18 months old.

The company launched a consumer version of Stork in August, but the new clearance will make Stork available with a prescription to continuously monitor babies at home as a medical device for healthy or sick babies. It can spot-check or continuously monitor SpO2 and pulse rate in babies, even in low perfusion conditions.

Stork relies on Signal Extraction Technology to reduce the risk of neonatal blindness from retinopathy of prematurity and improve screening for critical congenital heart disease. Storks patented sensor technology nests within a silicon boot available in three sizes.

BTIG analyst Marie Thibault is "bullish" on Stork, estimating it addresses a $500m market opportunity in the "premium" part of the $1.5bn baby-monitoring market. "This represents an an adjacent market opportunity that is closest to Masimo's strengths in healthcare technology."

Twin Health Lands $50M To Support Whole Body Digital Twin Tech

Twin Health secured $50m to support expansion of its Whole Body Digital Twin, a digital artificial intelligence model of individuals' unique metabolisms.

The funding is led by Temasek with support from existing investors Iconiq Growth, Sofina, Peak XV, and Helena.

"The funding will help propel our strategy to scale the availability of our transformative technology and the way it's deployed to even more health plans and employer partners, achieving lower costs, better outcomes and higher satisfaction among their members and employees," says Twin Health CEO Jahangir Mohammed.

The company previously raised $187.3m over four rounds, including a $140m series C in 2021. (Also see "*Can Digital Twin Technology Help Beat Chronic Disease? Twin Health Is Getting Users Hooked, And Off Their Meds*" - Medtech Insight, 1 Nov, 2023.)