Podcast Name: *ACM ByteCast*
Episode: 57. Mary Lou Jepsen

Welcome to the *ACM ByteCast* podcast, a series from the Association for Computing Machinery! The podcast features conversations with researchers, practitioners, and innovators at the intersection of computing research and practice about their experiences, lessons learned, and visions for the future of computing. In this episode, host Scott Hanselmen is joined by Dr. Mary Lou Jepsen, CEO and founder of Open Water. Her extensive portfolio includes 250 patents and over 50 products

To begin, Dr. Jepsen explains that patents are not only intellectual achievements but also crucial tools in manufacturing. She discusses how patents provide indemnification when working with contract manufacturers, allowing companies to produce and ship products efficiently without owning their own factories. Jepsen outlines the immense challenges faced in developing novel medical technologies. On average, it takes 13 years and $658 million to secure regulatory approval for a new therapeutic device. This slow process prevents the industry from leveraging advancements in Moore's Law and contract manufacturing. Open Water is developing innovative imaging technology using infrared light, ultrasound, and electromagnetics to diagnose and potentially treat diseases, including cancer and severe depression.

Dr. Jepsen recounts her decision to leave her high-level role in augmented and virtual reality at Facebook to focus on healthcare. She saw a major opportunity in applying technological advancements to leapfrog traditional drug-based treatments. Open Water aims to create general-purpose imaging machines that can be adapted for multiple medical applications. Their technology has already demonstrated success in glioblastoma, depression, and neurodegenerative diseases. Open Water is leveraging advanced miniaturized hardware, including custom lasers and ultrasound transducers, to create cost-effective medical devices.

Open Water has had a major breakthrough in stroke detection. Stroke is the second leading cause of death worldwide, and large vessel occlusion strokes are especially deadly if not treated within two hours. Dr. Jepsen describes how Open Water has developed an innovative portable diagnostic tool—akin to an ECG for the brain—that can detect LVO strokes rapidly and guide emergency responders to appropriate hospitals. This device could significantly improve survival rates and recovery outcomes by expediting treatment. The focus then shifts to cost reduction in medical devices. Dr. Jepsen has reduced the cost of her system from $1 million to $10,000, with expectations to lower it further to $1,000. Research and medical innovation often fail to reach clinical practice due to high costs and regulatory barriers. She argues for a model that enables faster production, wider accessibility, and greater profitability through volume rather than high individual costs.

Open Water's device designs are open source, allowing others to build them while ensuring compliance with regulatory standards. Their technology is ISO 1345 approved, IRB ready, and FDA ready for clinical trials. By making the hardware accessible, the company ensures transparency while still maintaining profitability by selling high volumes of units. A discussion

follows on why traditional medical devices, like MRIs and CT scans, remain large and expensive despite advancements in other technologies. Jensen highlights a breakthrough approach for treating cancer non-invasively using ultrasound at diagnostic-safe levels. Unlike traditional therapies that damage healthy tissue, this method selectively targets cancer cells by identifying their resonant frequency.

The discussion moves toward the next steps in clinical trials. Dr. Jepsen explains that she has successfully tested their method in mice, achieving remission in 30 cases without harming healthy cells. There are ongoing efforts to refine the approach, including potential biopsy-based personalized treatments. The technology is expected to be in clinical use by the next quarter, and the speaker acknowledges a growing number of patients eagerly awaiting treatment. In closing, Dr. Jepsen criticizes the current healthcare coverage system, where expensive treatments are often reserved for the wealthy, and patients must fight for coverage. She highlights the fact that the #1 percent of bankruptcy in the U.S. is from medical bills. Despite this, Dr. Jepsen closes out on a positive note looking toward the future of possibilities with open source.

Key takeaways:
0:00 - Welcome to *ACM ByteCast.*
0:40 - The Role of Patents in Manufacturing.
3:58 - Regulatory and Technological Barriers in Healthcare Innovation.
5:51 - Founding Open Water and the Vision for Scalable Medical Imaging.
9:40 - Breakthroughs in Stroke Diagnosis and Treatment.
14:33 - Reducing Medical Device Costs and Scaling Production.
19:52 - Non-Invasive Cancer Treatment Using Ultrasound.
21:28 - Clinical Trials and Future Prospects.
27:36 - Challenges in Healthcare Accessibility and Systemic Issues.
33:30 - Discussing the Ethics Review Panel and IRBs.

Links
Learn more about Dr. Mary Lou Jepsen.
Learn more about the ACM ByteCast podcast at https://learning.acm.org/bytecast