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## **Analysis and Select Evidence and Testimony:**

### **Innovative Health v Biosense Webster Unit of Johnson & Johnson**

#### **Overview**

The jury trial began in the U.S. District Court for the Central District of California on May 6, 2025, and the jury reached its verdict on May 16, 2025, after two hours of deliberation.

They returned a [verdict in favor of Innovative Health](#) (IH) on claims for unlawful tying under Section 1 of the Sherman Act, unlawful monopolization under Section 2 of the Sherman Act, attempted monopolization under Section 2 of the Sherman Act, and unlawful tying under California's Business and Professions Code, the Cartwright Act.

The jury awarded Innovative damages in the amount of \$147,406,481.00, which was automatically trebled to \$442,219,443.00 under the Cartwright Act. The Court entered judgment in favor of Innovative on June 5, 2025. Judge James Selna presided over the case.

Only July 31, Judge Selna issued [an order](#) granting IH injunctive relief and barring Biosense Webster (BSW) from continuing most of the practices the jury found to be unlawful. The details of the injunction are still being determined, and we anticipate a final ruling in mid-August.

#### **Analysis of the Case**

The case centers on three main strategies that BSW used to limit hospitals' use of FDA-regulated, reprocessed devices from Innovative Health (and Stryker's Sustainability Solutions), which instead forced hospitals to use virgin single-use devices sold by BSW.

#### **I) Unlawful Tying of BSW Case Coverage, CARTO 3 Mapping System, and Catheters**

When a seller forces a buyer to purchase a second, distinct product as a condition of buying the first product, courts may consider that an illegal "tying" practice. Some tying arrangements can violate antitrust laws because it can restrict competition and consumer choice.

In this case, BSW tied its CARTO 3 Mapping System of case support (an expert in mapping for cardiovascular procedures that was employed by BSW but worked in the surgical suite) to the purchase of BSW virgin catheters and refused to provide case support when competing reprocessed devices were used in the procedure.

Evidence was presented indicating that BSW wove a multi-pronged strategy the court found to be unlawful: they poached independent mappers from hospitals, withheld training from non BSW

personnel, instituted non-compete clauses with those they did train and used software updates to prevent others from learning the system.<sup>i</sup>

By hiring away independent mapping experts, hospitals became more reliant on BSW provided mappers. BSW ultimately reached, as evidence seems to suggest, 95% case coverage with their own reps. When BSW adopted its case coverage policy (to stop providing support when competing reprocessed devices were used) in conjunction with making themselves indispensable (as hospitals had a shortage of independent reps), the hospitals had no choice but to stop reprocessing to ensure continued case support from BSW. In some cases, the mappers left the surgical suite during procedures when surgeons selected IH catheters. As clinicians depend on the CARTO 3 system for many procedures, this policy effectively eliminated hospitals' ability to choose reprocessed devices.<sup>ii</sup>

According to witness testimony, BSW targeted over 200 hospitals that had been using IH catheters for its strategy of tying case coverage to the mapping system and BSW catheters.<sup>iii</sup> Evidence and testimony revealed that BSW did not disclose its Case Coverage Policy in contracts, with some hospitals not finding out about the policy until years after their contract was signed.<sup>iv</sup> BSW's Case Coverage Policy was found to have significantly increased costs according to one expert's testimony<sup>v</sup> and frustrated hospitals who preferred to use the reprocessed catheters.<sup>vi</sup>

In his tentative ruling on the permanent injunction, Judge Selna has instructed BSW to cease its policy of not providing case support when reprocessed devices are use.

### **Key Testimony: Unlawful Tying, Case Support and Single-Use OEM Catheters**

*"I'm not a fan [of Biosense Webster's Case Coverage Policy]...It stops us from being able to meet our goal of making healthcare affordable to everyone. We're paying full price for something that we can get at a fraction of the cost."* ~Testimony of Mary Roberts, Providence St. Joseph Health System<sup>vii</sup>

*"We want to use the reprocessed Pentaray catheters, but Biosense says that they will stop covering our cases if we begin using those...While I'd like to just tell them to (^&\*% off, we are dependent on them."*

~Email from Ken Blenis, MarinHealth Medical Center<sup>viii</sup>

*"[Biosense Webster] has not been upfront with us from the beginning. The clinical rep feeds the physicians with nonsense about the reprocessed catheters from [competitors] being sub-par, which has been tested and proven not to be the case...They consistently tell us one thing, and then when agreements are signed, they tell us we misunderstood and it ends up costing us much more. They are not a business partner and I do not trust them at all."*

~Email from Portia Tranguch, Allegheny General Hospital<sup>ix</sup>

*"[CARTO 3 is a] must-have product. If you want to do a CARTO 3 procedure, you must have a mapper. And [Biosense] had other products that some customers wanted to buy from independent reproducers. And instead of competing in those markets, [Biosense] implemented the Case Coverage Policy, which tied access to their mappers to the purchase of [their] catheters."*

~Testimony of Dr. Eric Forister, Econ One<sup>x</sup>

*“[T]he hospitals that wanted to use reprocessed [devices] were forced instead to buy much more expensive new [devices], and so the price they faced went way up. [Additionally], Biosense, by excluding competition, was able to continue to inflate its own prices for new [devices].”*

**~Testimony of Dr. Eric Forister, Econ One<sup>xi</sup>**

*“Ascension didn't like it. They tried to move their business elsewhere, but they couldn't. Ultimately what happened, even though Ascension didn't like it, was Ascension spent another \$4 million with Biosense because of the [tie]...[Ascension] didn't want it. They wanted to buy from independent reproprocessors. And so this wasn't competition on the merits. This was about eliminating choice and reducing or harming competition.”*

**~Testimony of Dr. Eric Forister, Econ One<sup>xii</sup>**

*“...the withholding of training from hospitals is one of the things that Biosense did to obtain the dominant position in the market for mappers, and it was its dominant position in the market for mapping that allowed it to force hospitals to buy its catheters...Biosense was poaching mappers from the hospitals, withholding training, instituting non-competes, and making software changes to block hospitals from mapping themselves.”*

**~Testimony of Dr. Eric Forister, Econ One<sup>xiii</sup>**

*"The CARTO 3 relies on software to perform the mapping, and so the mappers are trained on a particular version of the software. If that software version changes, the mappers would need new training in order to continue mapping. And so one of the blocking tactics that Biosense undertakes is to...change that software so that existing mappers at hospitals can no longer do mapping."*

**~Testimony of Dr. Eric Forister, Econ One<sup>xiv</sup>**

## **2) BSW Used Forced Obsolescence Strategies Like “Blocking” or “Kill” Chips in Certain Catheters to Stymie Reprocessors**

Reprocessors have long accused some original equipment manufacturers of inserting “kill” chips into devices that serve no other purpose but to render the product unusable after its initial use. Reprocessing companies spend significant time and money to reverse engineer kill chips, often losing months of time in the marketplace. In this case, evidence demonstrates BSW inserted the chips specifically to delay reprocessors’ ability to compete.

In his tentative ruling on the permanent injunction, Judge Selna sides with IH that the chipping practice must stop.

### **Key Testimony: Forced Obsolescence and Kill Chips**

*“[T]he main driver of implementing the [chip] is preventing our competitors [from reprocessing devices] and not...to reprocess them ourselves.”*

**~Internal email from Mario Garcia, J&J MedTech<sup>xv</sup>**

*“From an OEM perspective, the suggested course of action is to innovate a “next -generation” [device] to obsolete the current catheter...”*

**~Internal email from Joseph Koenig, J&J MedTech<sup>xvi</sup>**

### 3) BSW Hoarded Used Catheters with the Intention of Choking Supply and Putting Reprocessors out of Business

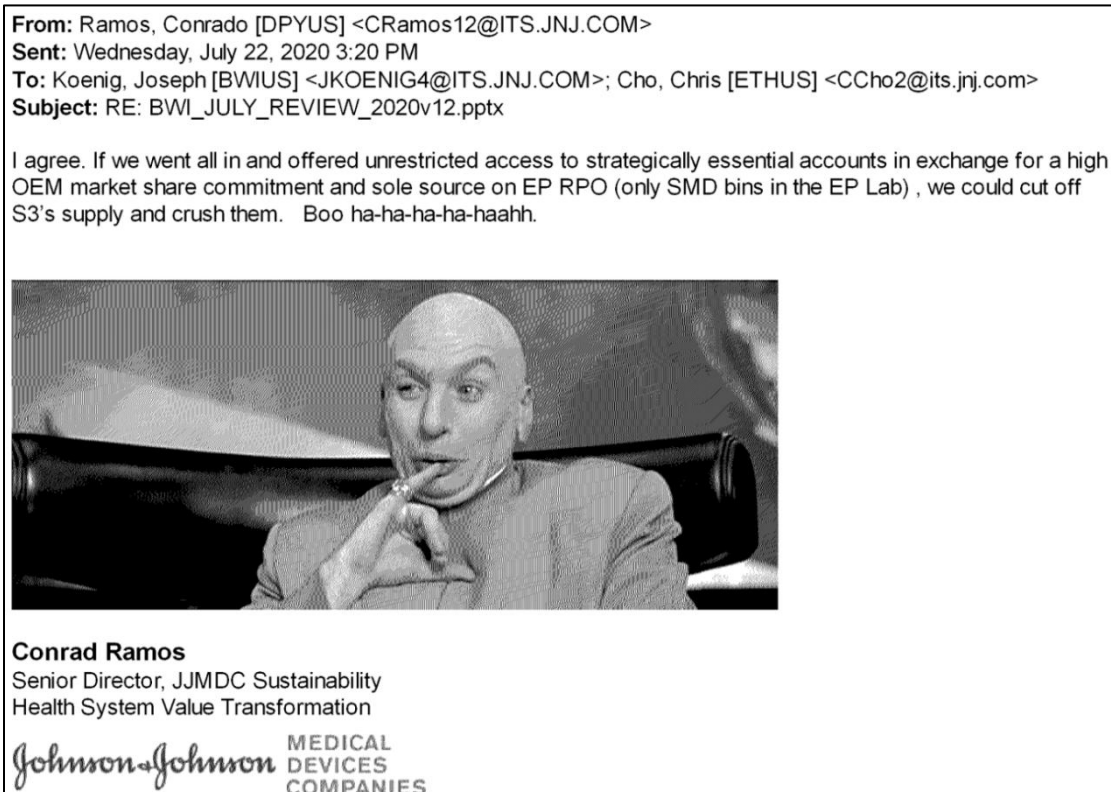
Evidence showed a business strategy by BSW to hoard used devices, particularly those that had FDA clearances for reprocessing, for no other reason than to prevent the devices from getting to reprocessors. One J&J sustainability representative used Dr. Evil (from Austin Powers fame) to illustrate the intention of the strategy.

#### Key Testimony: Hoarding

*“If we control...collections, we control the market. In fact...we could drive [Stryker’s Sustainability Solutions] out of the [EP reprocessing] business altogether.”* ~J&J MedTech staff, internal slide<sup>xvii</sup>

*“If we went all in and offered unrestricted access to strategically essential accounts in exchange for a high OEM market share commitment and sole source on EP RPO (only SMD bins in the EP lab), we could cut off [Stryker’s Sustainability Solutions’] supply and crush them. Boo ha-ha-ha-ha-haahh.”*

~Internal email from Conrad Ramos, Senior Director, Sustainability, J&J MedTech (screenshot below)<sup>xviii</sup>



## **Permanent Injunction**

Although the permanent injunction remains open to comments from both parties, Judge Selna is expected to finalize the ruling in mid-August. He has indicated he intends for the permanent injunction to:

- prohibit tying clinical support services to catheter purchases;
- ban the future use of anti-reprocessing “kill switches” (also called “Falcon chips”) that disabled BSW devices once used;
- block BSW from hoarding used catheters to prevent reprocessors from lawfully obtaining source materials; and
- remove BSW’s control of managing a toll-free complaint line and awards Innovative Health the right to manage it instead, at its expense, if it chooses.

Terms of the ruling are to be in effect for five years.

## **About the Selected Evidence and Testimony**

AMDR has abridged quotes for readability, and provided citations where full, unabridged quotes may be found in the case docket, which is publicly available on PACER. Page numbers (within the footnotes) correspond to those in the PDF in which a quote was found.

*“[None of BSW’s activities] – the blocking technology, the collection and withholding, and the Case Coverage Policy – none of those things made Biosense’s products better. They just eliminated or restricted the choice of customers to buy their preferred catheters, which happened to be offered by other companies.”*

**~Testimony of Dr. Eric Forister, Econ One<sup>xix</sup>**

## **Resources Available for Hospitals**

For more information, as well as practical guidance for how hospitals can recognize and [report](#) anticompetitive activities, please visit AMDR’s [dedicated webpage](#) about the case.

## **About Reprocessing**

Reprocessing refers to the cleaning, testing, and repackaging of “single-use” medical devices that are regulated by the FDA or similar national regulatory authorities so they may be returned for reuse by hospitals and clinics.

The practice applies to over 300 types of “single-use” devices that are FDA-cleared or regulated and carry a CE mark in the EU, because regulatory authorities have found the reprocessed devices to be as

safe and effective as the original device. Reprocessing occurs off-site from hospitals, at AMDR-member commercial reprocessing facilities.

Use of reprocessed devices is one of the most celebrated innovations in the healthcare industry because use of these devices simultaneously cuts costs and the environmental footprint for hospitals. Reusing devices also strengthens the supply chain by keeping these medical device assets closer to home, minimizing reliance on products shipped from overseas and the materials used to create them. Over a dozen countries have regulatory frameworks that oversee and allow reprocessed devices.

These benefits have led the most prestigious hospitals in the world to embrace reprocessing to provide better care through smarter use of resources.

Today, nearly 9,400 hospitals and surgical centers worldwide (including the Mayo Clinic, Cleveland Clinic, all *US News & World Report* “Top Hospitals,” and 74 U.S. military hospitals) are reducing costs, waste, and greenhouse gas emissions, while strengthening the healthcare supply chain – by working with AMDR-member regulated, commercial reprocessing companies.

### **About AMDR**

The Association of Medical Device Reprocessors ([AMDR](#)) is the global non-profit trade association for the regulated, commercial “single-use” device reprocessing and remanufacturing industry. AMDR members serve over 9,400 hospitals and surgical centers in the U.S., Canada, Europe, Japan and Australia.

Founded in 1997, AMDR advocates for reprocessing and remanufacturing as an important healthcare strategy that helps hospitals and healthcare providers to strengthen the supply chain while simultaneously reducing costs, waste, and emissions. AMDR protects the interests of its members in regulation, legislation, and standard-setting.

AMDR protects the interests of its members in regulation, legislation, and standard-setting. AMDR members include [Arjo ReNu Medical](#), [Innovative Health](#), [Medline ReNewal](#), [Stryker’s Sustainability Solutions](#), [Sustainable Technologies](#) (a Cardinal Health Business), [Vanguard AG](#), and [Vein360](#). Having played a key role in the establishment of the reprocessing industry, AMDR continues to push the global medical technology industry, leading the way for remanufacturing to play a defining role in the evolution of new device technologies.

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<sup>i</sup> Trial Tr. Day 5 (testimony of Dr. Eric Forister). *Innovative Health LLC v. Biosense Webster, Inc.*, Doc 571-1 p. 470

<sup>ii</sup> Trial Tr. Day 5 (testimony of Dr. Eric Forister). *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 548-7 p. 11

<sup>iii</sup> Trial Tr. Day 4 (testimony of Meredith Snider). *Innovative Health LLC v. Biosense Webster, Inc.*, Doc 571-1 p. 440

<sup>iv</sup> Trial Tr. Day 5 (testimony of Dr. Eric Forister). *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 548-7 pp. 32-33

<sup>v</sup> *Ibid.*, pp. 19-21

<sup>vi</sup> *Ibid.*, p. 15

<sup>vii</sup> Trial Tr. Day 3 (testimony of Mary Roberts). *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 535-1 p. 222

<sup>viii</sup> Email from Ken Blenis to Jay Farris re: EP Cath reprocessing. *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 571-1 p. 271

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- <sup>ix</sup> Email from Portia Tranguch to Robert Pezzin re: Biosense Webster-Clinical Support Policy review with AGH. *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 556-1 p. 18
- <sup>x</sup> Trial Tr. Day 5 (testimony of Dr. Eric Forister). *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 548-7 p. 11
- <sup>xi</sup> *Ibid.*, pp. 20-21
- <sup>xii</sup> *Ibid.*, p. 15
- <sup>xiii</sup> Trial Tr. Day 7 (testimony of Dr. Eric Forister). *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 571-1 p. 586
- <sup>xiv</sup> Trial Tr. Day 5 (testimony of Dr. Eric Forister). *Innovative Health LLC v. Biosense Webster, Inc.*, Doc 571-1 p. 472
- <sup>xv</sup> Email from Mario Garcia to HTC team re: Vizigo EEPROM. *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 535-1 p. 66
- <sup>xvi</sup> Email from Joseph Koenig to Marius Fine re: BWI DecaNav reprocessed Cath. *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 571-1 p. 261
- <sup>xvii</sup> Biosense Webster slide presentation. *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 535-1 p. 44
- <sup>xviii</sup> Trial Tr. Day 3 (testimony of Conrad Ramos). *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 535-1 p. 244
- <sup>xix</sup> Trial Tr. Day 5 (testimony of Dr. Eric Forister). *Innovative Health LLC v. Biosense Webster, Inc.*, Doc. 535-1 p. 157