UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA, SOUTHERN DIVISION

INNOVATIVE HEALTH LLC,

Plaintiff,

vs.

BIOSENSE WEBSTER, INC.,

Defendant.

Case No. 8:19-cv-1984 JVS (KES)

PERMANENT INJUNCTION [585]

JUDGE: HON. JAMES V. SELNA
COURTROOM: 10C

Action Filed: October 18, 2019
Trial Date: May 6, 2025

This Court has considered the materials and arguments submitted by the parties regarding Plaintiff Innovative Health LLC's Motion for Permanent Injunction, as well as the full record in this matter, including the trial record and the jury's verdict for Plaintiff. Pursuant to 15 U.S.C. § 26, Cal. Bus. & Prof. Code § 16750(a), and this Court's equitable powers, the Court hereby GRANTS Innovative's Motion for Permanent Injunction and ORDERS that Defendant Biosense Webster, Inc. be enjoined as follows:

1. **Definitions**

1.1. "**Biosense**" means Defendant Biosense Webster, Inc. and its officers, agents, servants, employees, attorneys, and all persons who receive actual notice of this injunction and are in active concert or participation with any of them. This definition includes Biosense Webster's parent company Johnson & Johnson, Johnson & Johnson subsidiary SterilMed, Inc., and their respective officers, agents, servants, employees, and attorneys. This definition is intended to bind all persons within the scope of Fed. R. Civ. P. 65(d)(2).

1.2. "**CARTO**" means any past, present, or future cardiac mapping machine made by or for Biosense, including the CARTO 3 and any new version of it (whether bearing the "CARTO" name or not).

1.3. "**Consumable**" means a device (including, but not limited to, an electrophysiology catheter) originally manufactured by Biosense for use with CARTO.

1.4. "**Clinical Support**" means the services provided to operate the CARTO by Biosense's clinical account specialists, including associate clinical account specialists and ultrasound clinical account specialists. For the avoidance of doubt, "Clinical Support" includes any service or activity that Biosense has refused to provide, pursuant to its Position Statement on Clinical Account Specialist Case Support of Reprocessed Single-Use Devices, to customers that sought to use Consumables sold by or for someone other than Biosense,

such as (i) assisting with reconstructing cardiac anatomy using CARTO, (ii) assisting with interpreting maps and providing insight on the images generated by CARTO, and (iii) providing technical support for CARTO and troubleshooting CARTO during a procedure. *See, e.g.*, JX-535; JX-216. Notwithstanding the foregoing, Clinical Support does not include making representations as to the accuracy, performance, or specifications of Consumables sold by or for someone other than Biosense, or the accuracy or specifications of maps or images created using those Consumables.

2. **No Tie.**

2.1. ***Tie Forbidden.*** Biosense is enjoined from conditioning the provision of Clinical Support—or otherwise conditioning the availability of CARTO—on the purchase or use of Consumables sold by or for Biosense.

2.2. ***Duty Not to Discriminate.*** Biosense is further enjoined from discriminating in the provision of Clinical Support or the availability of CARTO because of the purchase or use of (or the intention to use) a Consumable of someone other than Biosense. Without limitation, and by way of example only, Biosense may not refuse, withdraw, or degrade the availability of Clinical Support or CARTO, or charge a higher price for Clinical Support or for the sale, lease, or use of CARTO, because a hospital or doctor has used, is using, will use, or may use a Consumable of someone other than Biosense. Nothing in this Section 2.2 requires Biosense to make representations as to the accuracy, performance, or specifications of a Consumable sold by or for someone other than Biosense, or the accuracy or specifications of maps or images created using those Consumables. For the avoidance of doubt, Biosense cannot withhold Clinical Support in any way on the ground that it does not or cannot make those representations.

3. **No New Blocking Technology.**

3.1. ***Definitions.*** "Technology" refers to any technology installed by or for

Biosense on CARTO, on hardware or software supporting the operation of CARTO or of any Consumable (*e.g.*, remote server), or on a Consumable. "New Technology" refers to any Technology that Biosense did not deploy by June 5, 2025, on or in connection with any product marketed or sold to consumers.

3.2. ***Blocking Technology Prohibited.*** Biosense is enjoined from implementing any New Technology that is intentionally designed to prevent or impede Consumables sold by or for someone other than Biosense from operating or functioning with CARTO. This injunction does not prohibit Biosense from installing any Technology that it had already deployed, by June 5, 2025, on any Consumable marketed or sold to consumers (*e.g.*, the Falcon chip installed on the Soundstar Eco) in other Consumables after that date.

4. **Limits on Collection of Consumables.**

4.1. ***No Collection of Consumables That Biosense Cannot Reprocess.*** Biosense is enjoined from collecting used Consumables which it does not have (i) regulatory approval to reprocess under section 510(k) of the Food, Drug and Cosmetic Act; or (ii) a pending application for approval to reprocess under section 510(k) of the Food, Drug and Cosmetic Act.

4.2. ***Exceptions.***

4.2.1. ***For 510(k) Test Devices.*** Notwithstanding Section 4.1, this injunction does not prohibit collecting a used Consumable to the extent necessary to support a 510(k) application to reprocess that Consumable.

4.2.2. ***For Investigating Defective Biosense Products.*** Notwithstanding Section 4.1, this injunction does not prohibit collecting a used Consumable that has not already been reprocessed by someone other than Biosense, to the extent necessary to investigate and remediate a defect in that Consumable.

4.2.3. ***For Ablation Catheters That Are Not Reprocessed.*** Notwithstanding

Section 4.1, this injunction does not prohibit Biosense from collecting ablation catheters that no other person reprocesses in the United States. If any person begins to market or sell a reprocessed version of a catheter subject to this Section 4.2.3, Biosense must comply with Section 4.1 with respect to that catheter within 30 days of notice of such marketing or sale, such as (i) the clearance on the FDA's 510(k) database or (ii) the approval listed on the FDA's Premarket Approval (PMA) database.

4.2.4. ***Exception***

Notwithstanding Section 4.1, this injunction does not prohibit Biosense from collecting a used Consumable from a customer who voluntary participates in collection efforts for purposes of recovering scrap value.

5. **Reports to the Court.** Every six months during this injunction's term, a Biosense executive with relevant knowledge and with responsibility for compliance with this injunction shall submit a report to this Court. The report shall (i) explain the executive's knowledge and responsibility for compliance with this injunction; (ii) detail the steps Biosense has taken to ensure compliance with this injunction; (iii) summarize the instances of potential noncompliance with this injunction of which Biosense is aware; (iv) describe the steps taken to investigate and remediate those instances of potential noncompliance; and (v) certify, under penalty of perjury, that Biosense continues to comply fully with this injunction.

6. **Notice.**

6.1. ***Notice of Injunction.*** Within 21 days of the entry of this injunction, Biosense shall notify all past and current CARTO users of this injunction. The notice shall specify that Biosense must provide Clinical Support to every customer or end user on nondiscriminatory terms and without regard to whether that person uses Consumables of someone other than Biosense.

6.1.1. ***Forms of Notice Required.*** Biosense shall give this required notice in

writing, in a form agreed to by Plaintiff or approved by the Court. The notice shall be sent to all persons who Biosense understands have responsibility for contracting or procurement on behalf of past or current customers who have or have had a CARTO. Biosense must also provide this written notice to every electrophysiology physician associated with those customers that currently have a CARTO.

6.1.2. ***New CARTO Purchasers.*** While this injunction is in effect, Biosense shall notify any purchaser of a CARTO of this injunction's terms. Biosense shall provide that notice in writing (i) with any proposed agreement to acquire a CARTO, and (ii) again once any CARTO is sold. Biosense shall give this required notice in a form agreed to by Plaintiff or approved by the Court.

6.2. ***Notice of Hotline.*** Innovative Health LLC or a third party designated by Innovative may establish, at their expense, a hotline for reporting actual or potential noncompliance with this injunction. Within 21 days of receiving notice from Innovative that such a hotline has been created, Biosense shall notify (i) its employees and (ii) past and current CARTO users of the hotline and its purpose. That notice shall include information about when and how reports can be submitted (*e.g.*, 24 hours a day, 7 days per week) and whether submitters can remain anonymous. Biosense shall also keep, in a prominent location on its internal systems accessible to its employees, the same information about the hotline and its purpose. The parties shall agree on the form of these notices by Biosense or, otherwise, shall submit competing proposals to the Court.

6.3. ***Notice to Sales Employees.*** Within 14 days of the entry of this injunction, Biosense must notify every sales employee, including all clinical account specialists (which in turn includes all associate clinical account specialists and ultrasound clinical account specialists), of their and Biosense's

obligations under this injunction. Biosense shall also notify any new sales employees, including all clinical account specialists, of this injunction within 10 days of the commencement of their employment. Biosense shall re-notify all sales employees of this injunction on an annual basis during the term of the injunction. The parties shall agree on the form of these notices by Biosense or, otherwise, shall submit competing proposals to the Court. Biosense shall maintain records sufficient to verify that Biosense has provided the notices required by this paragraph.

7. **Term of Injunction.** This injunction shall take effect when this Court enters the final judgment. It shall remain in effect for five years from the date of entry. Either party may move to modify, extend, or terminate this injunction for good cause. The Court expressly reserves the power to adjust the term of the injunction, whether to shorten or lengthen it, to reflect ongoing market conditions and changes therein.

8. **Retention of Jurisdiction.** This Court retains jurisdiction of this matter and the parties with respect to this injunction, including (i) to address any disputes or requests for direction regarding this injunction's construction, modification, termination, or extension; (ii) to enforce, modify, terminate, or extend this injunction; and (iii) to assess and to punish violations of this injunction.

IT IS SO ORDERED.

DATED: August 27, 2025

The Honorable James V. Selna
United States District Judge