UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

REDACTED CIVIL MINUTES - GENERAL

Case No.	8:19-cv-1984-JVS (KESx)	Date	March 22, 2022
Title	Innovative Health LLC v. Biosense Webster, Inc.		

Present: The Honorable	**James V. Selna, U.S. District Court Judge**

Lisa Bredahl	Not Present
Deputy Clerk	Court Reporter
Attorneys Present for Plaintiffs:	Attorneys Present for Defendants:
Not Present	Not Present

Proceedings: **[IN CHAMBERS] REDACTED Order Regarding Defendant Biosense Webster's Motion for Summary Judgment [114]**

Defendant Biosense Webster ("Biosense") moves for summary judgment as to all claims brought by Innovative Health LLC ("Innovative Health" or "Innovative"). See Mot., Dkt. 114; Sealed Mot., Dkt. 139. Innovative opposes the motion. See Opp'n, Dkt. 131; Sealed Opp'n, Dkt. 146. Biosense filed a reply in support of its motion. See Reply, Dkt. 154; Sealed Reply, Dkt. 156.

The Court held a hearing on this Motion on February 28, 2022. See Dkt. 168.

For the following reasons, the Court **GRANTS** the motion. The Court asks the parties to meet and confer and notify the Court which parts of the order should be redacted within seven days.

I. BACKGROUND

A. Factual Background

1. The Parties

Biosense is a California corporation that manufactures and sells the CARTO 3 cardiac mapping system and electrophysiology ("EP") products, including catheters, that can be used with that system. Pl.'s Statement of Genuine Disputes ("SGD"), Dkt. 146-1, ¶ 1. Cardiac mapping systems create detailed, 3D anatomical maps of the heart and its

electrical signals, which physicians use to diagnose and treat arrhythmias. Id. ¶ 16; Dkt. 115 at 11, ¶ 4 ("Thomas Decl."). Biosense is the original equipment manufacturer ("OEM") of three catheters at issue in this litigation: the Lasso NAV ("Lasso") catheter, Pentaray catheter, and SoundStar catheter. Id. ¶ 2. It also sells those catheters. Id.

Innovative Health is an Arizona company that reprocesses and sells EP catheters that can be used with cardiac mapping systems. Id. ¶ 8. It began selling reprocessed catheters in 2017. See Resp. to Statement of Genuine Disputes ("RSGD"), Dkt. 156-1, ¶ 11. Innovative markets itself as a low-cost provider that offers cost-savings for catheters. Id. ¶ 12. Innovative Health manufactures reprocessed versions of Biosense's Lasso, Pentaray, Soundstar catheters, among other EP catheters. Id. ¶ 13.

2. Relevant Electrophysiology Devices and Procedures

Biosense introduced its current cardiac mapping system, the CARTO 3 to the U.S. market in 2009. Id. ¶ 14. CARTO 3 only works with navigational catheters that were originally designed and manufactured by Biosense. Wu Dep. 76:11–76:19, SUF ¶ 18. The three Biosense catheters presently at issue—the Lasso, Pentaray, and SoundStar catheters—are all sensor-enabled catheters that work with the CARTO 3. Id. ¶ 18. Biosense's Lasso Catheter is a circular mapping catheter that provides high-resolution mapping. Id. ¶ 19. The Pentaray catheter is Biosense's high-density mapping catheter that provides advanced, multi-electrode mapping capabilities. Id. ¶ 20. And, Biosense's SoundStar catheter is an ultrasound catheter with the addition of a magnetic sensor for mapping functionality. Id. ¶ 21. The SoundStar connects to the CARTO 3 in addition to an ultrasound system, which allows a physician to incorporate an ultrasound image into the 3D anatomical map generated on CARTO 3. Id.

The accuracy of the 3D map created on CARTO 3 during an EP procedure can affect the success and safety of the procedure. Id. ¶ 22. Biosense calibrates its sensor-enabled catheters in order to ensure uniform location references across catheters. Id. ¶ 23. Proper catheter calibration is important to ensure patient safety. Id. ¶ 24.

3. FDA Regulation of Reprocessing

The FDA began regulating the reprocessing of single-use medical devices in 2000.

Id. ¶ 25. All manufacturers—including original manufacturers and reprocessors—must apply for clearance to market Class II medical devices pursuant to section 510(k) of the Food, Drug and Cosmetic Act. Id. ¶ 26. The FDA bases its decision as to whether to grant a Premarket Approval application under 510(k) on whether the device is "substantially equivalent" to a legally-marketed device. Id. ¶ 27 (quoting section 513(I) of the FD&C Act (21 U.S.C. § 360c(I))). For purposes of FDA regulations, Innovative, not Biosense is the legal manufacturer of its reprocessed Biosense catheters. Id. ¶ 29.

4. Competing Manufacturers

Biosense's principal competitors for the sale of cardiac mapping systems are Abbott Laboratories ("Abbott") and Boston Scientific Corporation ("Boston Scientific"). Id. ¶ 44.

In 2009, Abbott's predecessor company, St. Jude, launched its EnSite Velocity cardiac mapping system ("Ensite Velosity"). Id. ¶ 45. In 2017, Abbott introduced the next generation of this system, the Ensite Precision system, which uses both impedance measurements and magnetic catheter tracking. Id. ¶ 46. Abbott manufactures the following catheters that are used to create 3D anatomical maps of the heart during EP procedures: Advisor HD Grid Mapping Catheter Sensor Enabled ("Advisor HD Grid" or "HD Grid") and the Advisor FL and Advisor VL catheters, among others. Id. ¶ 47. Abbott also manufactures the ViewFlex ICE ultrasound catheter, which is compatible for use with Abbott or Philips ultrasound systems. Id. ¶ 48.

In 2013, Boston Scientific released the Rhythmia cardiac mapping system ("Rhythmia"), which also uses a combination of magnetic and impedence-based technology to create cardiac maps. Id. ¶ 49. Boston Scientific manufactures the following catheters that are used to create 3D anatomical maps of the heart during EP procedures: INTELLAMAP ORION, Constellation, and Orbiter PV. Id. ¶ 50. Boston Scientific also manufactures the Ultra ICE Plus ultrasound catheter for use with its iLAP ultrasound ICE system. Id. ¶ 51.

Biosense also competes with new entrants in the cardiac mapping industry, including the following companies that have introduced cardiac mapping systems since 2017: Acutus Medical, Inc. ("Acutus") (2017 - AcQMap), Medtronic pls

("Medtronic") (2017 - CardioInsight), Philips North America LLC ("Philips") (2018 - KODEX-EDP), APN Health LLC ("APN") (2018 - Navik 3D) and CardioNXT, Inc. ("CardioNXT") (FDA clearance 2021 - iMap). Id. ¶ 52. Acutus manufactures the AcQMap 3D Imaging and Mapping Catheter used to create 3D anatomical maps of the heart during EP procedures. Id. ¶ 53. Philips manufactures an ICE ultrasound catheter, the VeriSight Pro, which is compatible with its EPIQ Cvx ultrasound system. Id. ¶ 54.

Biosense also competes for the sale of mapping and ultrasound catheters with manufacturers who reprocess those catheters. Id. ¶ 55. For example, Stryker manufactures reprocessed EP catheters, including mapping and ultrasound catheters originally manufactured by Biosense and Abbott. Id. ¶ 56.

5. Biosense Clinical Support

Clinical support is the operation of the cardiac mapping system during a cardiac mapping procedure. Id. ¶ 130. It is industry standard for OEMs to provide free support in the medical device industry, including in the EP industry. Id. ¶ 131. Historically, most hospitals provided their own clinical support ("self-support") for CARTO 3 and its predecessor, the CARTO XP. Id. ¶ 132. Biosense provides its clinical support to customers for free and always has. Id. ¶ 133. Biosense covers the cost of clinical support with revenue from its products, including catheters. Id. ¶ 134.

Biosense employees called Clinical Account Specialists ("CAS") operate the CARTO 3 software to build the 3D anatomical and electrical map of the patient's heart using the data sent from all of the catheters used by the phsyician during an EP procedure. Id. ¶ 135. In 2009, approximately 50 percent of CARTO procedures did not rely on Biosense's support. Id. ¶ 136. By 2020, the percentage of CARTO 3 cases that Biosense CAS supported increased to approximately 95 percent. Id. ¶ 137. From 2009 to 2020, Biosense increased its CAS headcount from approximately 120 to approximately 900 CAS. Id. ¶ 138.

Biosense trains its CAS team through an internal training program. Id. ¶ 139. It incurs significant costs each year to train and employ CAS to provide clinical support. Id. ¶ 140. Biosense estimates that deploying a CAS costs approximately [redacted] per CARTO 3 procedure. Id. ¶ 144. Biosense has no contractual or other obligation to

provide clinical support. Id. ¶ 145. The parties have identified eight hospitals that currently self-support some or all EP procedures on CARTO 3. See id. ¶ 148 (listing hospitals).

6. Innovative Clinical Support and Clinical Support Training

As early as January 2017, Innovative recognized that providing mapping assistance would aid it in selling its reprocessed SoundStar, Lasso, and Pentaray catheters. Id. ¶ 150. However, Innovative does not provide clinical support to its customers because it is not economically feasible. Id. ¶ 151. For example, when asked if Innovative could provide clinical support if it charged the same price as Biosense, Innovative's Vice President of Business Development, Dave Distel testified,

> [a]nd how would that work? If I charged the same amount, why would—why would the hospital—by selling reprocessing I'm selling a substantially equivalent product that allows the hospital to save significant money while maintaining clinical outcomes. If I'm selling it for the same price, that's been neutralized.

Id. ¶ 152. Innovative employed a qualified mapping technician to develop its clinical support program. Id. ¶ 153. Innovative provided MedStar Health with a technician to support its reprocessed sensor-enabled catheters for less than two months through a pilot project. Id. ¶ 154.

Innovative markets self-support as a viable option for hospitals that want to purchase Innovative's sensor-enabled catheters. Id. ¶ 158. Innovative tells hospital customers that "[r]eprocessing cost savings can finance the cost of independent mapping techs and add savings for the EP lab." Id. ¶ 159. Its marketing materials state that "employing a hospital technician can save a lab more than $500k per year" because annually it would cost approximately $100,000 to employ a mapping technician and hospitals can save approximately $630,000 by switching to Innovative reprocessed sensor-enabled devices. Id. ¶ 160.

Innovative's CFO testified that the company has the financial resources to offer a clinical support training program. Id. ¶ 163. Innovative offered to provide direct clinical

support or clinical support training for CARTO 3 cases using its reprocessed sensor-enabled catheters to at least thirteen hospitals. See id. ¶ 164 (listing hospitals). Only one customer, MedStar Health utilized Innovative's mapping support for a few months, but ultimately elected not to continue using it. Id. ¶ 165. Innovative has now decided against offering clinical support for the CARTO 3. Id. ¶ 166.

7. Biosense's Clinical Support Policy

Biosense's clinical support policy prohibits its CAS from (a) creating a 3D map with a non-Biosense sensor-enabled catheter or (b) interpreting an ultrasound image in a procedure that utilizes a non-Biosense ultrasound catheter. Id. ¶ 167. That policy applies to the Lasso, Pentaray, and SoundStar catheters, which are all sensor-enabled catheters. Id. ¶ 168. But Biosense's clinical support policy does not prevent hospitals from providing self-support or prevent third parties from providing clinical support for a CARTO 3 procedure. Id. ¶ 169. Biosense began to implement a formal, written position statement regarding clinical support in late 2014. Biosense distributed the policy statement to customers throughout 2015 and into 2016 to ensure compliance by April 1, 2016. Id. ¶ 172. In response to reports of inconsistent enforcement of the clinical support policy in 2016, Biosense retrained field staff on the policy to ensure compliance, requiring full implementation by April 1, 2016. Id. ¶ 173.

B. Procedural Background

Innovative Health's operative Corrective Second Amended Complaint ("CSAC") asserts eight causes of action under Sections 1 and 2 of the Sherman Act and California's Cartwright Act. The Court previously dismissed Innovative Health's exclusive dealing claims in its Fourth Sixth, Tenth, and Twelfth Causes of Action. See Mot. to Dismiss Order, Dkt. 45.

II. LEGAL STANDARD

Summary judgment is appropriate where the record, read in the light most favorable to the nonmovant, indicates "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); see also Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). Summary adjudication, or

partial summary judgment "upon all or any part of [a] claim," is appropriate where there is no genuine dispute as to any material fact regarding that portion of the claim. Fed. R. Civ. P. 56(a); see also Lies v. Farrell Lines, Inc., 641 F.2d 765, 769 n.3 (9th Cir. 1981) ("Rule 56 authorizes a summary adjudication that will often fall short of a final determination, even of a single claim . . . .") (internal quotation marks omitted).

Material facts are those necessary to the proof or defense of a claim, and are determined by referring to substantive law. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In deciding a motion for summary judgment, "[t]he evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." Anderson, 477 U.S. at 255.[1]

The moving party has the initial burden of establishing the absence of a material fact for trial. Anderson, 477 U.S. at 256. "If a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact . . ., the court may . . . consider the fact undisputed." Fed. R. Civ. P. 56(e)(2). Furthermore, "Rule 56[(a)] mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp., 477 U.S. at 322. Therefore, if the nonmovant does not make a sufficient showing to establish the elements of its claims, the Court must grant the motion.

III. DISCUSSION

A. Market Definition

Innovative Health argues that there are four product markets at issue: (1) navigational ultrasound catheters for use with the CARTO 3; (2) high-density mapping catheters for use with the CARTO 3; (3) circular mapping catheters for use with

[1] "In determining any motion for summary judgment or partial summary judgment, the Court may assume that the material facts as claimed and adequately supported by the moving party are admitted to exist without controversy except to the extent that such material facts are (a) included in the 'Statement of Genuine Disputes' and (b) controverted by declaration or other written evidence filed in opposition to the motion." L.R. 56-3.

the CARTO 3; and (4) clinical support for the CARTO 3. See Opp'n, Dkt. 146, at 17–20. Biosense argues that all of Innovative Health's claims fail because it cannot define and prove any legally cognizable "relevant markets." See Mot., Dkt. 139, at 11.

"A threshold step in any antitrust case is to accurately define the relevant market, which refers to 'the area of effective competition.'" Fed. Trade Comm'n v. Qualcomm Inc., 969 F.3d 974, 992 (9th Cir. 2020) (internal citation omitted); see also Image Tech. Servs., Inc. v. Eastman Kodak Co., 125 F.3d 1195, 1202 (9th Cir. 1997) ("The relevant market is the field in which meaningful competition is meant to exist." (citing United States v. Continental Can Co., 378 U.S. 441, 449 (1964))). "Market definition is an essential predicate to the entire case, for '[w]ithout a definition of [the] market there is no way to measure [the defendant's] ability to lessen or destroy competition.'" Reilly v. Apple Inc., 2022 U.S. Dist. LEXIS 3661, at *9 (N.D. Cal. Jan. 7, 2022) (quoting Ohio v. Am. Express Co., 138 S. Ct. 2274, 2285 (2018) (alterations in original); Flagship Theatres of Palm Desert, LLC v. Century Theatres, Inc., 55 Cal. App. 5th 381, 413 (2020) (noting the same under California's Cartwright Act).

"The definition of an antitrust 'relevant market' is typically a factual rather than a legal inquiry, but certain legal principals govern the definition." Apple Inc. v. Psystar Corp., 586 F. Supp. 2d 1190, 1196 (N.D. Cal. 2008) (citing Newcal Indus., Inc. v. Ikon Office Solution, 513 F.3d 1038, 1045 (9th Cir. 2008)). To define a market, the Court must determine: (1) "the field in which the plaintiff was engaged . . . in geographic and distributional terms," and (2) "the product (or product line) that competes in that field." Optronic Techs., Inc. v. Ningbo Sunny Elec. Co., 2021 U.S. App. LEXIS 35876, at 28 (9th Cir. 2021) (quoting JBL Enters., Inc. v. Jhirmack Enters., Inc., 698 F.2d 1011, 1016 (9th Cir. 1983)). A product market comprises "products that have reasonable interchangeability for the purpose for which they are produced—price, use and qualities considered." United States v. E.I. duPont de Nemours & Co., 351 U.S. 377, 406 (1956). "Including economic substitutes ensures that the relevant product market encompasses 'the group or groups of sellers or producers who have actual or potential ability to deprive each other of significant levels of business.'" Newcal Indus., 513 F.3d at 1045 (quoting Thurman Indus. Inc. v. Pay 'N Pak Stores, Inc., 875 F.2d 1369, 1374 (9th Cir. 1989)).

2. Single-Brand Markets

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Innovative Health alleges three catheter markets—including separate markets for navigational ultrasound catheters, high-density mapping catheters, and circular mapping catheters—as well as a market for CARTO 3 clinical support. Grossbard Decl., Ex. 122, Excerpted Forister Report ¶ 8(a), (c), (f), (I). Biosense contends that these are improper single-brand product aftermarkets for specific devices and support service for the CARTO 3. See Mot., Dkt. 139, at 11. Instead, it argues, the relevant market is the foremarket for cardiac mapping systems, and competition for the catheters at issue occurs across those substitutable systems. See id. at 14. Accordingly, Biosense concludes that Innovative Health must raise a triable issue with regard to the required conditions in the foremarket, which it has not done. See Reply, Dkt. 156 at 8.

Innovative argues that the markets it defines are not single-brand markets because "Biosense is not the only provider in these markets" as "Biosense, Stryker, and Innovative provide the catheters at issue." Opp'n, Dkt. 146, at 22–23. But that is not the case. Biosense, Stryker, and Innovative all provide the same Biosense catheters for use with the CARTO 3 (i.e., Lasso, Pentaray, and SoundStar). The fundamental difference is that Biosense manufactures and sells new catheters whereas Stryker and Innovative sell reprocessed units of the same products. See RSGD ¶¶ 2, 13. Each of the three catheter markets that Innovative purports to define includes only one product from one brand (Biosense). And because the CARTO 3 can only be used with Biosense's catheters and Innovative limits each market to catheters "for use with the CARTO 3," these catheters are not interchangeable with ones from other brands. This is precisely the definition of a single-brand market; that there are other resellers of the single-brand product does not change this. See Eastman Kodak Co. v. Image Tech. Servs., 504 U.S. 451, 459, 477 (1992) (defining a single-brand market for service and replacement parts for Kodak-brand photocopiers despite there being other providers of Kodak parts and service).

"Determining whether a single-brand market is proper requires 'a factual inquiry in to the 'commercial realities' faced by consumers." Epic Games, Inc. v. Apple Inc., 2021 U.S. Dist. LEXIS 172393, at *220 (N.D. Cal. Sept. 10, 2021) (quoting Eastman Kodak, 504 U.S. at 482). "Single-brand markets are, at a minimum, extremely rare" and courts have rejected single-brand market definitions "[e]ven where brand loyalty is intense." Apple, Inc. v. Psystar Corp., 586 F. Supp. 2d 1190, 1198 (N.D. Cal. 2008) (internal quotation marks and citation omitted). In fact, "[i]t is an understatement to say that single-brand markets are disfavored. From nearly the inception of modern antitrust law,

the Supreme Court has expressed skepticism of single-brand markets[.]" In re Am. Express Anti-Steering Rules Antitrust Litig., 361 F. Supp. 3d 324, 343 (E.D.N. Y. 2019).

Despite this, single-brand markets "are not per se prohibited, . . . [i]n theory, it may be possible that in rare and unforeseen circumstances, a relevant market may consist of only one brand of a product." Apple, 586 F. Supp. 2d at 1198. The Supreme Court explained in Eastman Kodak Co. v. Image Technical Services, Inc., that "one brand of a product can constitute a separate market" where customers are "locked in" by their purchasing decision in the primary market such that they are unable to switch to a competing brand in response to an allegedly anticompetitive policy change with respect to aftermarket products used with the system. 504 U.S. 451, 482, 477 (1992). Specifically, Kodak pointed to evidence of significant (1) "information costs"—the difficulty customers faced in adequately assess the total lifecycle costs of the equipment, parts and services when they purchased the photocopier; and (2) "switching costs"—customers' ability to respond to changes in the aftermarket by returning to the foremarket and purchasing a different brand copier. Id. at 455. Based on these conditions, the Supreme Court concluded that the market for replacement parts and services for Kodak copiers was a cognizable relevant market. See id. Notably, however, "[c]ourts have been extremely reluctant to embrace Kodak's single-brand market theory." In re ATM Antitrust Litig., 768 F. Supp. 2d 984, 997 (N.D. Cal. 2009) (internal quotation marks omitted).

The Ninth Circuit has identified four factors that indicate whether an alleged market is a properly defined single-brand aftermarket under Kodak: (1) the market is "wholly derivative from and dependent on the primary market"; (2) the "illegal restraints of trade and illegal monopolization relate only to the aftermarket, not to the initial market"; (3) the defendant's market power "flows from its relationship with its consumers" and the defendant did "not achieve market power in the aftermarket through contractual provisions that it obtains in the initial market"; and (4) that "[c]ompetition in the initial market . . . does not necessarily suffice to discipline anticompetitive practices in the aftermarket." Newcal, 513, F.3d at 1049–50.

Innovative's construct partially satisfies the Newcal test. The first factor is satisfied because the demand for Biosense's catheters and clinical support derive from its CARTO 3 system. Second, Innovative is only challenging alleged restraints that relate to

the aftermarkets for catheters and support, not for cardiac mapping systems. Third, because (i) Biosense's CARTO 3 system only works with its catheters, (ii) Biosense's clinical support and catheters only work with the CARTO 3 system, and (iii) CARTO 3 customers do not contractually agree to obtain catheters and support only through Biosense when they purchase the system, Biosense's market power flows from its relationship with consumers and it did not achieve market power in the aftermarket through contractual provisions that it obtains in the initial market. See Epic Games, 2021 U.S. Dist. LEXIS 172303, at *227 (finding that the third factor was met when customers did not contractually agree to obtain apps only through the App Store when purchasing an iPhone, developers were contractually restricted in the aftermarket, and "in light of the technical restrictions on iOS devices, Apple's market power flow[ed] from its relationship with its consumers and Apple did not achieve market power in the aftermarket through contractual provisions that it obtain[ed] in the initial market").

However, Innovative has not necessarily established the fourth element, that "[c]ompetition in the initial market . . . does not necessarily suffice to discipline anticompetitive practices in the aftermarket." See Newcal, 513, F.3d at 1049–50. "Issues of lock-in or switching costs, and notice or consumer knowledge, fall under the analysis of evaluating whether competition in the initial market suffices to discipline anticompetitive practices in the aftermarkets. Epic Games, 2021 U.S. Dist. LEXIS 172303, at *227.

Here, Biosense claims that "the evidence shows that: (1) competition occurs acrosss systems; (2) system switching costs are low, if they exist at all; (3) hospitals are sophisticated consumers who consider the cost of disposables in their system purchasing decisions; and (4) there is no evidence that the clinical support policy constitutes a Kodak-style "policy change" that takes advantage of "locked in customers." Mot., Dkt. 139, at 14. (citing SUF at ¶¶ 57–129). The Court evaluates each of these points below.

i. Policy Change

First, Innovative attempts to show lock-in based on Biosense's case coverage policy that it fully implemented by April 2016. According to the Position Statement by which Biosense announced the new policy to its customers, Biosense "can only provide clinical support for cases that use catheters they have been trained to support." Opp'n,

Dkt. 146, Ex. 82 at 418206. In practice, this prohibits coverage of cases in which the physician uses catheters with magnetic sensors like SoundStar, Pentaray, and Lasso, that have been reprocessed by third parties like Stryker and Innovative. See RGDF ¶ 168. But Biosense does provide clinical support on cases using other Biosense catheters that have been reprocessed by third parties.

"The breadth of antitrust law on the issue has counseled that currently 'to establish a single-brand aftermarket under Kodak and Newcal, the restriction in the aftermarket must not have been sufficiently disclosed to consumers in advance to enable them to bind themselves to the restriction knowingly and voluntarily.'" Epic Games, 2021 U.S. Dist. LEXIS 172393, at *226. However, this does not necessarily require a post-purchase policy change. See Newcal, 513 F.3d at 1048 (explaining that "[m]arket imperfections" may "prevent consumers from discovering" that purchasing a product in the foremarket could restrict their freedom to shop in the aftermarket"); Red Lion Med. Safety, Inc. v. Ohmeda, Inc., 63 F. Supp. 2d 1218, 1231 (E.D. Cal. 1999) ("Information costs may be high, and a manufacturer may thus have considerable market power in the aftermarket, even in the absence of a change in policy."). "In other words, a plaintiff must show evidence 'to rebut the economic presumption that [defendant's] consumers make a knowing choice to restrict their aftermarket options when they decide in the initial (competitive) market to' purchase in the foremarket." Epic Games, 2021 U.S. Dist. LEXIS 172303, at *226 (quoting Newcal, 513 F.3d at 1050). Thus, "it is only the customers who learned about the [allegedly anticompetitive policy] after purchasing their equipment that are relevant to the 'locked-in' analysis." DSM Desotech, Inc. v. 3D Sys. Corp., 749 F.3d 1332, 1346 (Fed. Cir. 2014).

The parties agree that Biosense's clinical support policy was known and enforced by April 1, 2016. RSGD ¶ 122. The evidence shows that many Biosense customers purchased their first CARTO 3 system after that date. Id. ¶ 122. For example, from November 2014 to March 2021, hospitals purchased 609 CARTO 3 systems. Id. ¶ 123. Of those 609 systems, 467 were purchased after April 2016, when the policy was widely known and enforced. Id. ¶ 124. While Innovative points to testimony from hospitals that they do not like Biosense's policy, it does not present evidence of any hospital purchasing a CARTO 3 system before learning of Biosense's clinical support policy, and then being locked-in. Further, Innovative has not presented evidence to show that any customer who purchased a CARTO 3 before the policy-change would have chosen not to

purchase the system had they known of Biosense's policy at the time of purchase. In contrast, Biosense has shown that its sales were not negatively affected by the policy rollout. In fact, its CARTO 3 system sales volume has consistently totaled approximately [redacted] systems sold per year before and after the policy was announced and implemented. SUF ¶ 123; Grossbard Decl., Ex. 33, BWI-INN00704867. Accordingly, Innovative has not demonstrated that the policy-change impacted a substantial number of preexisting customers such that they were locked-in. See SMS Sys. Maint. Servs., Inc., 188 F.3d at 21 (noting that under Kodak, "unless a substantial number of preexisting customers are locked-in, defections from the manufacturer's installed base, coupled with losses in the foremarket . . . will sabotage any effort to exploit the aftermarket.").

ii. System-Level Competition

The market reality is that Biosense faces robust competition as one of seven competitors in the market for mapping systems. See RGDF ¶¶ 44–46, 49, 52, 57–88, 90, 92, 99, 100–111. The parties have not produced any evidence to the contrary. See id. ¶¶ 59–68 (showing that Innovative Health's executives and sales team agree that there is competition between mapping systems and catheters). Biosense's principal competitors for the sale of cardiac mapping systems are Abbott Laboratories ("Abbott") and Boston Scientific Corporation ("Boston Scientific"). Id. ¶ 44. This is demonstrated by marketing materials and testimony from all three companies. Id. ¶¶ 70–80. And, Biosense also faces competition from various new entrants who have entered the market since 2017. Id. ¶¶ 52–54.

iii. Switching Costs

As to switching costs, the Supreme Court stated in Kodak that "[i]f the cost of switching is high, consumers who already have purchased the equipment, and are thus 'locked in,' will tolerate some level of service-price increases before changing equipment brands." 504 U.S. at 576. "Under this scenario, a seller profitably could maintain supra competitive prices in the aftermarket if the switching costs were high relative to the increase in service prices, and the number of locked-in customers were high relative to the number of new purchasers." Id.

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Innovate points to the significant cost of acquiring a CARTO 3 as evidence of significant switching costs. See, e.g., Opp'n, Dkt. 146, at 24. The CARTO 3 system's purchase price is more then [redacted] and its trade-in price is [redacted]. Opp'n, Ex. 43, Dkt 146-3, 2020 Commercial Pathways, at 2. Customers can also rent the system for approximately [redacted] per year. Id. at 3. If a customer does not have a CARTO 3, it can pay for the system through the purchase of catheters [redacted] at negotiated prices. Id. at 2. Biosense attempts to show that this significant sticker price does not amount to high switching costs for three main reasons: (1) many Biosense customers already have access to competing cardiac mapping systems to which they can switch at no cost; (2) the evidence shows that hospitals can and do switch between systems; and (3) aggressive competition between manufacturers for system placements in hospitals means that customers can acquire these systems with little or no capital outlay.

The evidence supports Biosense's assertion that hospitals often have access to competing systems. For example, Biosense's internal competitive intelligence reflects that approximately [redacted] of Biosense customers with a CARTO 3 system also have at least one competing cardiac mapping system onsite. Id. ¶ 93. Representatives from all six hospitals deposed testified that their hospitals or hospital systems have cardiac mapping systems from more than one manufacturer. Id. ¶ 95. Innovative Health's witnesses also testified that numerous hospitals have cardiac mapping systems from more than one manufacturer. Id. ¶ 96. Further, an analysis of Biosense's, Abbott's, and Boston Scientific's internal cardiac mapping system data performed by Compass Lexecon, a third-party neutral jointly retained by the parties ("Overlap Analysis"), found that approximately [redacted] of hospitals with a CARTO 3 system also have an Abbott Ensite Precision system and/or a Boston Scientific Rhythmia system. Id. ¶ 90 (citing Grossbard Decl., Ex. 121, Dkt 142-53 ("Overlap Analysis") at 1–2).[2]

[2] The Court acknowledges Innovative's warning that because Compass used Abbott's reported sales volume since 2013 instead of its installed base of systems, this number "would overstate Abbott's installed base to the extent that some systems purchased since 2013 would have been subsequently traded in or otherwise discarded." However, Innovative has provided no evidence of systems sold since 2013 being traded in or discarded and this number is notably close to Biosense's internal estimate. See RGDF ¶ 90.

Biosense argues that because many of its customers already have access to at least one competing cardiac mapping system, there would be no costs for those customers to switch from the CARTO 3 system to another system they already have. RSGDF ¶ 89. In response, Innovative counters that "[t]here is no evidence that CARTO 3 customers have significant excess capacity to switch to alternative mapping systems at their facilities if they have alternative mapping systems." Id. To the extent that hospitals do not have excess capacity to accommodate their cardiac-mapping needs with their existing alternative CARTO 3 systems, Innovative is correct that they would need to acquire a new alternative machine to do this. And, of course, there would be a cost associated with this switch. However, as there is no direct evidence that CARTO 3 customers have sufficient excess capacity to switch to alternative mapping systems at their facilities, there is no evidence that they do not.

Even so, the evidence shows that hospitals can and do switch from CARTO 3 to other competing systems when they choose to. To the extent that they have shifted studies and procedures to their existing alternative systems, this suggests that these hospitals were not restricted by capacity when deciding to do so. But, even when a hospital has switched or admits that it could switch to a competing system, that implies that the switching costs are not prohibitive—regardless of whether the hospital already had an alternative system or acquired a new one. For example, [redacted] Id. ¶ 106. In addition, [redacted] Id. ¶ 107. As another example, Cheryl Saxby, the Associate Vice President for Specialty Sourcing at Providence St. Joseph Hospital, testified that Providence "has been able to shift some system coverage, some mapping system coverage, away from the CARTO 3 system" and that it "could shift more system coverage away from the CARTO 3 if it chose to do so." RGDF ¶ 109. Likewise, Mary Roberts, the Director of the Clinical Resource Integration Department at Providence, also testified that it is within Providence's control to shift procedures and EP studies to other mapping systems in response to Biosense's policies. Id. ¶ 110. And finally, Portia Tranguch, Director of Cardiac Services at Allegheny General Hospital, testified that if Allegheny was

dissatisfied with Biosense's prices or system, it could switch cases to one of its other cardiac mapping systems. Id. ¶ 111. However, Tranguch also testified that Allegheny would not switch to another cardiac mapping system to save on reprocessed devices "because [she] believe[d] that the physicians [would] continue to use the [CARTO 3] system." Id. ¶ 112; Opp'n, Dkt. 131-2, Ex. 17, at 34:21–35:12.

Despite the system's over [redacted] purchase price, customers can acquire a CARTO 3 cardiac mapping system with less capital outlay through a commitment to purchase a minimum number of catheters; a system lease; a system rental; or a free 90-day system evaluation. Grossbard Decl., Ex. 18, Dkt. 142-2 ("2020 Commercial Pathways"), at 2–3. Biosense's competitors also offer similar programs to assist facilities in acquiring cardiac mapping systems. RGDF ¶¶ 101–103 (describing similar programs to acquire [redacted] and Acutus AcQMap cardiac mapping systems); ¶ 104 (collecting testimony from hospital witnesses confirming that cardiac mapping system manufacturers offer programs that allow hospitals to acquire their systems with little or no capital outlay). Innovative counters that rentals or leases can still cost roughly [redacted] and that catheter purchase programs do not eliminate the underlying costs to acquire the system. See, e.g., RGDF ¶¶ 100–104.

iv. Information Costs

With regards to information costs, the Supreme Court in Kodak explained that "[f]or the service-market price to affect equipment demand, consumers must inform themselves of the total cost of the 'package'—[in Kodak that included] equipment, service, and parts—at the time of purchase' that is, consumers must engage in accurate lifecycle pricing." Kodak, 504 U.S. at 473. The Court explained that "[i]f the costs of service are small relative to the equipment price, or if consumers are more concerned about equipment capabilities than service costs, they may not find it cost efficient to compile the information." Id. at 474–75.

Biosense has presented evidence from Innovative, group purchasing organizations ("GPOs") and hospital customers reflecting that hospitals are sophisticated customers that consider the life-cycle cost of a cardiac mapping system at the time of purchase. Id. ¶ 113. Various hospital witnesses testified that their hospitals project the lifecycle costs of cardiac mapping systems, including the number of projected cases and costs of

disposables when deciding whether to purchase a system. Id. ¶¶ 116–119. For instance, a representative from the Mayo Clinic testified that his hospital conducts a cost analysis when purchasing a cardiac mapping system that takes into account utilization, caseload, maintenance and the cost of disposables such as catheters that will be used in connection with the system. Id. ¶ 116. Even Innovative's Matt Dambeck testified that hospitals are sophisticated customers and that hospitals' Value Analysis Teams and Value Analysis Committees research prices for system and device purchases. Id. ¶ 114. Many hospitals purchase cardiac mapping systems through GPOs, which negotiate agreements to lower the cost of medical supplies on behalf of member organizations. Id. A former GPO employee testified that he considered the members of his former GPO to be sophisticated purchasers that assess life-cycle costs and make informed decisions about purchasing. Id. ¶ 115.

Given that hospitals are sophisticated repeat customers, Innovative has not shown that they are "locked in" because of high information costs that prevent them from accurately assessing lifecycle pricing when purchasing a cardiac mapping system. See SMS Sys. Maint. Servs. v. Digital Equip. Corp. 188 F.3d 11, 23 (1st Cir. 1999) ("Sophisticated consumers with such preferences will know beforehand that they will lock themselves in by their choice of manufacturer and do so willingly"). Further, in Kodak the Court reasoned that aftermarket service and replacement parts were low compared to the cost of the photocopier, and thus that it would be inefficient for consumers to evaluate those costs when deciding to purchase the equipment. 504 U.S. at 474–75. In contrast, here, hospitals spend more on catheters than they do on the cardiac mapping system itself. RGDF ¶ 97. And, because hospitals are sophisticated repeat customers, they know this will be the case before making the purchase. Id. Accordingly, Innovative cannot establish the high information costs preventing lifecycle pricing to establish a single-brand product under Kodak.

v. Physician Preference

Innovative Health argues that hospitals are locked in by their physicians' preferences for different cardiac mapping systems. To support this assertion, Innovative presents evidence that there is strong physician preference for different cardiac mapping systems and corresponding catheters. See Tuttle Dep. 10:1–25, Coldiron Dep. 22:2–23:19. Specifically, they point to testimony that phsyicians prefer to stay with a

particular system if "they've been trained on it" and "they've had good outcomes." Id. Biosense does not contest that physicians put up a "high bar" to switching systems due to their comfort with a particular system. Opp'n, Dkt 146, Ex. 26 at 3. One hospital witness testified that their hospital, [redacted], tried but was unsuccessful in getting its physicians to switch systems due to physician preference for the existing system. RGDF ¶ 108.

However, customer preference or brand loyalty does not amount to a company "locking in" customers for purposes of Kodak. See, e.g., Green Country Food Market, Inc. v. Bottling Group, 371 F.3d 1275, 1282 (10th Cir. 2004) ("Even where brand loyalty is intense, courts reject the argument that a single branded product constitutes a relevant market"); SMS Sys. Maintenance Servs., 188 F.3d at 24 (explaining that certain consumers preferences for a particular brand "does not translate into the kind of economic power that antitrust law aims to mitigate" and thus does not demonstrate lock-in under Kodak); Apple Inc. v. Psystar Corp., 586 F. Supp. 2d 1190, 1198 (N.D. Cal. 2008) ("Single-brand markets are, at a minimum, extremely rare" and courts have rejected such market definitions "[e]ven where brand loyalty is intense."); United States v. Oracle Corp., 331 F. Supp. 2d 1098, 1131 (N.D. Cal. 2004) ("Customer preferences towards one product over another do not negate interchangeability"). There is no evidence that brand loyalty is unique to Biosense. Accordingly, physicians' preferences for certain systems does not contribute to whether customers are locked in under Kodak.

vi. SSNIP Test

Innovative contends that its proposed market definitions are supported by the SSNIP analysis conducted by its expert, Dr. Forister. Opp'n, Dkt. 146, at 22–23; see also Forister Report, Dkt. 146-1. However, Biosense argues that Dr. Forister's SSNIP test is not relevant and does not properly measure cross-elasticity of demand . Reply, Dkt. 156, at 10.

"[A] SSNIP analysis asks whether a monopolist in the proposed market could profitably impose a small but significant and nontransitory price increase." Theme Promotions, Inc. v. News Am. Marketing FSI, 546 F.3d 991, 1002 (9th Cir. 2008) (internal citation omitted). This involves "an iterative analysis" in which one "proposes a candidate market, simulates a monopolization of that market, then adjusts the candidate

market and reruns the simulation as necessary." Sidibe v. Sutter Health, 2019 WL 2078788, at *27 n.204 (N.D. Cal. May 9, 2019) (quoting FTC v. Advoc. Health Care Network, 841 F.3d 460, 473 (7th Cir. 2016)).

Dr. Forister's SSNIP test is irrelevant to the single-brand market analysis here. The question here is whether the foremarket conditions that Newcal requires are present. Specifically, whether the foremarket is sufficiently competitive so as to discipline competition in the aftermarket. See Newcal, 513, F.3d at 1050. Instead, Dr. Forister's analysis incorrectly skips this threshold question and starts with the aftermarket products. As the Court explains above, there is robust competition in the foremarket for cardiac mapping systems. See supra Section III.A.2.ii. In fact, the evidence shows that all of the cardiac mapping systems in the foremarket have a reasonable interchangeability of use. See GDF ¶¶ 58–88; id. ¶ 92 ("The Abbott Ensite Precision, Boston Scientific Rhythmia and Biosense CARTO 3, as well as a number of other competing systems, can all be used to perform the same EP procedures"). The competing systems, including new entrants and existing machines, can take away business from Biosense. Id. In fact, there is evidence of actual switching between systems. See supra Section III.A.2.iii. That means that substantial foremarket competition for cardiac mapping systems is sufficient to discipline the competition in the aftermarkets for catheters and support. Innovative cannot raise a triable issue of fact by offering an expert opinion that contradicts the evidentiary record. See Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 242 ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when undisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict.").

Further, even if the Court were to consider Dr. Forister's analysis, the SSNIP test is fatally flawed because it does not actually measure cross-elasticity of demand. Instead, it depends entirely upon the market being one model of the original manufacturer's catheter and the reprocessed version of that same catheter. This analysis ignores cross elasticities of demand between the various catheters provided by different manufacturers. Accordingly, Dr. Forister's SSNIP test does not do anything to indicate that there are in fact separate product markets. See, e.g., Hicks v. PGA Tour, Inc., 897 F.3d 1109, 1123 (9th Cir. 2018) (affirming dismissal of antitrust claims because plaintiffs' alleged submarkets "omit[ted] many economic substitutes," were "not natural," "artificial," and "contorted to meet their litigation needs"). Finally, Dr. Forister's SSNIP Test only looks

at average prices. See, e.g., Forister Report, Dkt. 146-1, ¶¶ 124, 126, 130, 135. Biosense contends that looking at pricing by multiple manufacturers "defeats the SSNIP assumption that one is testing whether a monopolist can raise prices without offsetting substitutability." Reply, Dkt. 156, at 12.

Ultimately, Dr. Forister's SSNIP analysis is irrelevant here because it does not evaluate whether the foremarket conditions described by Kodak and Newcal are present and does not actually measure cross-elasticity of demand.

vi. Market Definition

Ultimately, there is robust competition in the foremarket, information costs are insignificant given the sophistication of hospital customers and the relatively low price of systems compared to aftermarket catheters, and Innovative has not shown that customers were locked in by a post-purchase policy change. Innovative has not shown that the significant information deficits and switching costs that locked in customers and ultimately justified defining a single-brand market in Kodak are present here. Accordingly, Innovative has not presented evidence sufficient to raise a triable issue of fact with regard to the required conditions in the foremarket to sustain its single-brand market definitions.

B. Clinical Support Market

Biosense argues that Innovative Health's four tying claims (Third, Fifith, Ninth, and Eleventh Causes of Action), fail "because [Innovative Health] cannot show that clinical support (the alleged 'tying' product) is a distinct product sold in a different market from the catheters supported (the alleged 'tied' product), as required to prove a tie." Mot., Dkt. 139, at 2.

Tying occurs when "the seller conditions the sale of one product (the tying product) on the buyer's purchase of a second product (the tied product)." Rick-Mik Enters. v. Equilon Enters., 532 F.3d 963, 971 (9th Cir. 2008) (internal quotation marks omitted). To prove a tying claim, a plaintiff must show "that there exist two distinct products or services in different markets whose sales are tied together." Eastman v. Quest Diagnostics Inc., "The essential characteristic of an invalid tying arrangement lies in the seller's exploitation of its control over the tying product to force the buyer into the

purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms." Eastman Kodak Co. v. Image Tech. Servs., Inc., 504 U.S. 451, 464 n.9 (1992) (internal quotation marks and alterations omitted).

"[T]o establish that a tying arrangement is illegal per se, plaintiffs must prove three elements: (1) a tie between two separate products or services sold in relevant markets; (2) sufficient economic power in the tying product to affect the tied market; and (3) an effect on a non-insubstantial volume of commerce in the tied product market. The test for determining whether there are two distinct products or services that compete in different markets is whether there is sufficient consumer demand for firms to offer the products separately. Jefferson Parish Hosp. Dist. No. 2 v. Hyde, 466 U.S. 2, 19 (1984), abrogated on other grounds by Ill. Tool Works Inc. v. Indep. Ink, Inc., 547 U.S. 28 (2006). To evaluate whether there is sufficient demand to support a separate market, courts look to whether, when given a choice, consumers purchase the tying and tied goods together or separately, and whether "competitive firms always bundle the tying and tied goods." Rick-Mik, 532 F.3d at 975.

First, Innovative cannot define and prove a single-brand market for clinical support for the same reasons it cannot establish single-brand markets for Biosense catheters. See supra III.A.2. This alone defeats Innovative's tying claims. See Newcal, 513 F.3d at 1044 n.3 (explaining that all claims under Sections 1 and 2 of the Sherman Act, including tying claims, require defining a relevant antitrust product market).

Separately, Innovative's tying claims fail because it cannot show that consumer demand is sufficient for firms to offer the products separately. The evidence shows that Biosense offers its clinical support for free with its cardiac mapping systems and always has. RGDF ¶ 133. It is not contractually required to provide the support. Id. ¶ 134. The parties also agree that it is industry standard that all cardiac mapping system manufacturers offer free support with their products. Id. ¶ 131. In fact, there is no evidence that any manufacturer has ever provided clinical support for another company's products, or has ever sold support for another manufacturer's catheters as a separate service.

Innovative argues that a separate market is demonstrated by the fact that various hospitals testified that they would purchase reprocessed catheters if Biosense would provide free clinical support for them.[3] The record does not show that there is sufficient demand from customers for each of the two products. Innovative also asserts that hospitals would provide their own clinical support if Biosense did not provide it for free—as demonstrated by the fact that hospitals historically provided their own clinical support before Biosense began offering it for free. However, this does not show that customers would rather pay for a product that they now get for free. In fact, that most hospitals have stopped providing their own support in favor of accepting the free support now that Biosense offers it shows that it is a value-add for Biosense customers. Also, that Biosense created a new industry standard of providing free clinical service with cardiac mapping systems shows that it was a competitive differentiation that has benefitted consumers.

In sum, Innovative has failed to establish any legally cognizable relevant markets to support its antitrust claims.

IV. CONCLUSION

For the foregoing reasons, the Court **GRANTS** the motion. The Court asks the parties to meet and confer and notify the Court which parts of the order should be redacted within seven days. Counsel shall lodge a proposed judgment within seven days.

IT IS SO ORDERED.

[3] But it must be noted that Biosense does provide support for other reprocessed catheters regardless who did the reprocessing; that would include not exclude Innovative's reprocessed Biosense catheters.