CIVIL MINUTES - GENERAL

Case No. SACV 19-01984JVS(KESx)

Date Dec. 11, 2020

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] Order Regarding Defendant's Motion to Dismiss

Defendant Biosense Webster, Inc. ("Biosense") moved to dismiss Plaintiff Innovative Health LLC's ("Innovative Health") corrected second amended complaint ("CSAC"). Dkt. No. 60. Innovative Health opposed the motion. Dkt. No. 61. Biosense then filed its Reply. Dkt. No. 69.

After the Court posted its tentative order, Biosense requested a hearing. Dkt. No. 70. Innovative Health then responded. Dkt. No. 72. The Court finds that no hearing is necessary, but has addressed certain concerns Biosense raised below.

For the following reasons, the Court **DENIES** the motion.

I. BACKGROUND

1. Factual Background

The background is drawn from the allegations in Innovative Health's CSAC. <u>See</u> CSAC, Dkt. No. 58. Only the portions of the factual background relevant to the instant motion are discussed.

This action involves a dispute between two competitors in the market for cardiac mapping systems and catheters. Biosense manufactures and sells the CARTO 3 cardiac mapping system and ultrasound catheters (SOUNDSTAR and ACUNAV) and high-density mapping catheters (PENTARAY and LASSO) for use with the system. Id. \P 2,

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The CARTO 3 cardiac mapping system tests the electrical activity of the heart to

diagnose abnormal heart rhythms. <u>Id</u>. ¶¶ 2, 6, 7. During the procedure, the physician uses a variety of catheters and relies on a technician to operate the mapping system software. <u>Id</u>. ¶¶ 6, 15.

Biosense describes itself as the "global leader" in cardiac mapping systems and has more than 50% of the systems installed in the United States. <u>Id</u>. ¶ 7. The FDA approved the CARTO 3 system for sale on October 13, 2009. <u>Id</u>.

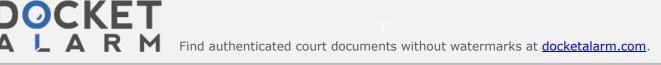
The FDA has also cleared Innovative Health to reprocess and sell the same catheters to hospitals one to three additional times for single use before disposal. Id. ¶¶ 1, 7.

i. Catheter Market

Innovative Health alleges that Biosense has monopoly power in the nationwide markets or submarkets for high-density mapping and ultrasound catheters for use with the CARTO 3 mapping system. CSAC \P 27. Specifically, Biosense has been able to charge supracompetitive prices for high-density mapping and ultrasound catheters. <u>Id.</u> Biosense has also maintained a dominant share of the market (estimated at 99%). <u>Id.</u> \P 28. Biosense also restricts output in the market and existing competitors lack the capacity to expand their output to effectively compete with Biosense. <u>Id.</u> \P 29-30.

Biosense has also caused significant barriers to entry in those markets. Id. ¶ 32. For example, "Biosense has ownership rights and exclusive licenses to patents blocking development of competing brands for use on the CARTO 3 system" and has brand name power as well. Id. ¶ 32. It has also "created a closed system for connecting high-density mapping catheters and ultrasound catheters." Id. ¶ 33. Biosense uses Because of encryption technologies on catheters. Id. ¶ 34. For third-party re-processors competing against Biosense, a change in Biosense's in encryption "during the development process, can add an additional 8 to 12 months to time needed to enter the market." Id.

Biosense also imposes additional barriers to entry into the catheter markets through its predatory conduct. Id. ¶¶ 37-51. For example, as a result of Biosense's training programs it "bires away clinical support personnel from the few hospitals handling their



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hospital has incurred the expense of training the specialist." <u>Id.</u> ¶ 41. As a result of then imposing noncompete agreements of 18 months or more on its own clinical account specialists, it is also able to limit the supply of qualified CARTO 3 Clinical Support specialists. <u>Id.</u>

ii. Clinical Support Market

In the CSAC, Innovative Health claims that a relevant service market exists for CARTO 3 clinical support. CSAC \P 8.

In the CSAC, Innovative Health discusses the role of CARTO 3 Clinical Support relative to the catheters Biosense also provides. Innovative Health alleges that this service is unique and difficult to provide. Specifically, "[i]f there is no CARTO 3 Clinical Support, the cardiac mapping procedure does not get done." <u>Id.</u> CARTO 3 Clinical Support requires the use of an expert to guarantee proper use of CARTO 3 hardware, software, and catheters. <u>Id.</u> These experts are hired by Biosense, which operates a clinical account specialist training program, including "extensive life classroom and one-on-one clinical training on the CARTO 3 that lasts 6 to 12 months." <u>Id.</u> According to Innovative Health, these experts "are not reasonably interchangeable with other allied health professionals, such as radiographers or sonographers," and hospitals "must use a trained CARTO 3 clinical support specialist for CARTO 3 procedures regardless of any price increase in CARTO 3 clinical support." <u>Id.</u>

Not only is CARTO 3 Clinical Support difficult to provide, but also, Biosense is "the only option for CARTO 3 clinical support" in "almost every hospital in the United States." Id. ¶ 9. "Very few hospitals provide their own CARTO 3 clinical support," and "on information and belief, California has just one hospital that provides its own CARTO 3 clinical support and has the capability to provide" similar training to what Biosense itself provides. Id. This is because hospitals do not have the ability to start their own CARTO 3 Clinical Support programs. Id.

Biosense also does not provide its training materials to hospitals so they can manage CARTO 3 themselves: "[u]pon information and belief, Biosense has not provided its own clinical account specialist training program or any comparable program with live classroom and one-on-one clinical training to hospitals to train their staffs to



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outside supplier to hospitals in the market for CARTO 3 clinical support" and "none of the other cardiac mapping system manufacturers offer clinical support, or training for clinical support, on the CARTO 3." Id. ¶ 10.

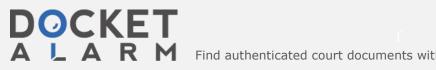
Innovative Health also alleges "relevant geographic markets or submarkets for CARTO 3 clinical support based on the geographic pods organized by Biosense to provide CARTO 3 clinical support in the United States." Id. ¶ 11. There are "hundreds of clinical account specialists" organized into these geographic pods. Id. "[O]ne or more clinical account specialists will service the cluster of labs in that pod or territory." Id.

iii. Separate Market

Innovative Health alleges a separate market for its catheter markets. <u>Id.</u> ¶ 19. "The prices of catheters are set independently of the price for clinical support" and Biosense even "sells catheters of all kinds without clinical support." Id. Hospitals also purchase other catheters – those not from Biosense – without clinical support. Id. ¶ 19. Moreover, hospitals even "prefer to purchase catheters separately from the clinical support and routinely do so in the absence of the case coverage policy." Id. Hospitals can realize "even larger cost savings on the higher-priced catheters" provided by Biosense by doing so. Id.

Historically, the aforementioned was the case, but Biosense has "since initiated a program more than ten years ago to provide clinical account specialists free of charge to provide case coverage to develop physician relationships, cultivate brand loyalty, and drive catheter sales." Id. ¶ 20. Since Biosense started this program, "nearly all hospitals have switched their CARTO 3 clinical support to Biosense and become accustomed to receiving CARTO 3 clinical support for free. They have also lost the capability to provide their own CARTO 3 clinical support or train their staff to do so." Id. ¶ 20.

Whereas CARTO 3 clinical support is not provided as part of the contract for the purchase of the CARTO 3 system, "Biosense has implemented a written policy of refusing to provide case coverage by its clinical account specialists in support of physicians at hospitals on cases with Biosense high-density mapping and ultrasound catheters reprocessed by competitors." Id. ¶¶ 19, 20. To that end, "Biosense will pull its clinical support for the CARTO 3 if the hosnital intends to use a high-density manning



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Once a hospital has purchased a cardiac mapping system – which Innovative Health claims Biosense is shielded from competition on the initial price – it is also likely to continue using the existing system. Id. ¶¶ 21-26. Hospitals do so not only because of Biosense's initial courting of hospitals by building relationships with them, but also because the CARTO 3 systems are "already used at their hospital and perceived to be the established standard of care at that hospital specifically or in their locale generally." Id. ¶ 25. Moreover, hospitals will hesitate to purchase a new cardiac mapping system given the enormous cost of doing so, and because "very few hospitals even have staff qualified to operate any cardiac mapping system to get trained for switching to a new system." Id. ¶ 26.

Biosense also provides clinical support for some catheters not provided by it. Id. \P 19.

2. Procedural Background

On August 18, 2020, the Court granted in part and denied in part Biosense's motion to dismiss. Dkt. No. 45. In addition to the matters described below, the Court granted the motion to dismiss the exclusive dealing causes of action. <u>Id.</u> at 11.

Thereafter, Biosense moved for partial reconsideration on other issues addressed in the Court's Order. Biosense claimed that while the Court dismissed the causes of action as they related to clinical support because Innovative Health failed to plausibly allege market power for clinical support, the Court erred in finding that Innovative Health could plausibly plead tying. Dkt. No. 46. The Court agreed, finding that Innovative Health needed to allege market power, but failed to do so, and granted Innovative Health ten days to submit a corrected second amended complaint. Dkt. No. 58. On October 16, 2020, Innovative Health filed its corrected second amended complaint. Dkt. No. 58. Biosense then moved to dismiss. Dkt. No. 60.

Innovative Health now asserts 12 causes of action against Biosense: (1) monopolization in violation of the Sherman Act, 15 U.S.C. § 2 (high-density mapping catheters); (2) attempted monopolization in violation of the Sherman Act § 2 (highdensity mapping catheters); (3) tying in violation of the Sherman Act § 1 (high-density mapping catheters): (4) exclusive dealing in violation of the Sherman Act § 1 (high-

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